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AN INVESTIGATION OF CHARACTERISTICS RELATED TO ELDERLY
NURSING HOME RESIDENTS' PARTICIPATION
IN PROPOSED RESEARCH

A Thesis
Presented for the
Master of Science in Nursing
Degree
The University of Tennessee, Knoxville

Douglas H. Walters

December 1987

This thesis is dedicated to a man who not too long ago told me about his life. He spoke of a time 17 years ago when he retired after a physician diagnosed him as terminally ill with one or two years to live. The man, wife, and five children moved South where he could breathe easier and have a simple happier life. Every night he prayed to God to let him live just long enough to see his youngest daughter graduate high school so that his duty as a father may be fulfilled.

Six years ago his daughter graduated high school; four years later he attended one son's college graduation ceremony and then performed as the best man in that same son's wedding. The man's voice started to quiver and tears swelled in his eyes as he explained that each and every day after his daughter's graduation he considers to be a "special day" given to him by God. He also proclaimed, "being happy is the only thing worthwhile in life."

This man passed away last summer. One may be able to imagine the enormous impact that conversation had on me. However, the impact made by that man on me is imperceivable, for that conversation would have to be multiplied thousands of times, over the past 25 years.

I love you dad. I am happy, living each and every day as if it was a "special day" given to me by God.

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In the course of thesis research, a number of people have assisted me generously. In particular, thanks go to Dr. Sandra P. Thomas, John Jozwiak, and Sally Helton, who served as my director and committee respectively. With their consultation, criticism, and encouragement, I was able to achieve results otherwise impossible.

I would like to thank the nursing home administrators of Knoxville Health Care Center and Hillcrest West for their permission to perform a research project with the residents. Thanks also go to Carolyn for her advice and revision time.

Family members have been especially helpful in many ways. Sue, my mother, even though in the process of grieving, found time and energy to encourage, critique, revise, and otherwise enhance an environment conducive for writing a thesis. Concern, support, and funds were faithfully provided by my wife, Nancy. In my most desperate time of need, Dan, Harlena, and Morgan welcomed me with open arms into their home.

ABSTRACT

The general problem involves a shortage of research studies on the institutionalized elderly. The purpose of this study was to determine which characteristics of elderly nursing home residents influence their participation in proposed research. Additionally, the researcher investigated the question: Does the complexity of a research consent form affect the participation rate of elderly nursing home residents in proposed research?

A total of 66 elderly subjects from two nursing homes participated in this study. Eligible subjects were initially identified by using a mental status test to screen out individuals with moderate to severe intellectual impairment. The eligible subjects were divided into two equal groups, one to receive a simple consent form and the other to receive a complex consent form. A comprehension test was immediately administered after collecting the consent form.

The researcher hypothesized that elderly nursing home residents who received a simple consent form would agree to participate in proposed research in greater numbers than those who received a complex consent form.

With the results obtained from data collection, the researcher rejected this hypothesis. In fact, for reasons undetected by this study, the elderly subjects signed the complex consent form in significantly greater numbers than they did the simple consent form. Recommendations for future research are offered.

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CHAPTER I

INTRODUCTION

Chapter I presents the problem, background information, need for the study, purpose of the study, research questions, subsidiary questions and definition of terms. The problem section describes the dilemma that arises when one attempts to perform research studies on an institutionalized elderly population.

The advancement of medical knowledge has resulted in longer life spans. This lengthened life expectancy has created a rapidly growing population of elderly people with the likelihood of serious medical problems (Ratzan, 1981). With the growing need for medical care aimed at this expanding population, research projects that examine and explore illnesses affecting the elderly will become increasingly necessary. Consequently, there is a greater need for the participation of the elderly in research projects. Researchers interested in studies involving the elderly population are increasingly aware of the need for well informed volunteers and the requirement to supply sufficient information to make decisions concerning their well being. Also, potential legal problems that could arise from providing inadequate information may

be avoided. It is important that researchers provide volunteers with adequate information concerning risks and benefits of research projects in clear and easily understood language.

Performing research in a nursing home setting is often frustrating to the investigators in their efforts to obtain informed consent from potential subjects. The reluctance of institutionalized residents to participate in research studies has not, to this researcher's knowledge, been formally investigated. It is the aim of this study to deal with the requisition of an informed consent from institutionalized elderly clients.

Problem

The general problem is a shortage of research studies involving the institutionalized elderly. The limited number of research projects suggests that this population may be difficult to study. In the literature that is available, some investigators complain that the institutionalized elderly have poor participation rates in proposed research studies (Hoffman, Marron, Fillit & Libow, 1983; Kelly & McClelland, 1979; Leader & Neuwirth, 1978; Makarushka & McDonald, 1979; Ratzan, 1981; Steinberg, Fitten & Kachuck, 1986). Thus, the question arises; why have

the institutionalized elderly had poor participation rates in proposed research studies?

Background Information

A major conflict for health care researchers involves the desire to examine diseases and suffering versus the desire to respect the integrity of the individual being studied (Cassidy & Oddi, 1986). Out of this controversy emerges the quest for subject consent, a voluntary act whereby an individual willingly agrees to participate in a research action or project (Reich, 1978). The next logical development involves the drafting of a consent form that will obtain informed consent from potential research participants. The ideal purpose of the consent process is to provide research candidates with sufficient relevant material to enable them to make an informed, intelligent decision regarding possible participation (Baker & Taub, 1983).

The concept of informed consent can be traced through early American law to its origins in English common law. In fact, specific consent to any intrusion upon one's body is one of the many requirements adopted by American courts from English common law (Berkowitz, 1978; Watson, 1982). The necessity of informed consent

in research studies was first formally recognized in the Nuremberg Code (Appelbaum & Roth, 1982).

Protection of the right to informed consent prior to participation in experiments was the major issue at the Nuremberg trials, which led to the Nuremberg Code in 1946. Stuart (1978) recounted that the Nuremberg Code established the following criteria for voluntary consent: (1) the person must legally be capable of giving consent; (2) the consent must be obtained without any element of fraud, duress, force, or deceit; and (3) the person must be offered sufficient knowledge of the experiment to ensure understanding of all anticipated consequences of participation in the research study. However, as Appelbaum and Roth (1982) pointed out, the code has no provision for any procedures that will permit subjects lacking in mental or physical capacity or competence to participate in research. Furthermore, Appelbaum and Roth maintained that the situation was altered by the Declaration of Helsinki in 1964, which categorizes research as either therapeutic or non-therapeutic. In each category the Declaration of Helsinki allows the consent of a third party to be substituted for that of an incompetent subject.

By 1979, as is recounted by Baker and Taub (1983), the requirements of informed consent were expanded to

include written information concerning the following:

(1) the nature and purpose of the study and the procedures; (2) the direct and indirect benefits that a volunteer would receive for participation; (3) the discomforts and potential risks associated with participation; (4) the availability of alternative procedures or therapies; (5) the readiness and willingness to discuss procedures and to answer all questions; (6) the right to refuse participation or to withdraw from participation at any time without prejudice; and (7) the rights, if any, to treatment or compensation for research-related injury. These requirements emanated from policies and guidelines that developed over the years after the Nuremberg Code and Declaration of Helsinki.

Need for the Study

The elderly population is growing at an overwhelming pace. There are approximately 28 million Americans over the age of 65 years (U.S. Bureau of Census, 1986), a figure that will probably double in the next 50 years (Butler, 1981). Presently, this older population constitutes 12 percent of the total American population but, however, accounts for 30 percent of all personal health care spending (U.S. Bureau of Census, 1986). Freeland, Calat and Schedler

(1980) calculated that this older group benefits from 55 percent of all federal health dollars. By the year 2030 it is possible that approximately 55 million persons, or in the range of one in seven to one in five Americans, will be age 65 years or older (Butler, 1981). Butler further forecasted that by 1990 the people residing in nursing homes will require more than triple the \$22 billion spent on their care in 1981.

These staggering figures signify a drastic need for an increase in research related to the elderly population, especially those residing in nursing homes. The increased need for more money, education, and manpower required to meet the needs of this expanding elderly population will clearly tax the current health care system (Steinberg et al., 1986). It is therefore clear that our health care system will have to be updated to meet the increasing needs of this expanding elderly population. If our health care system is to be effective, further investigation of nursing home residents may be required.

However, before an increase in research of the elderly can occur, studies must be initiated to ascertain reasons why the institutionalized elderly are being so adamant in their refusal to participate in research. Only 44 (66 percent) of the 67 eligible persons asked gave written consent to participate in

Kelly and McClelland's (1979) non-invasive study, which involved only questionnaire completion. Hoffman, Marron and Libow (1983) attained a smaller percentage of consents for participation in a study involving venipuncture; only 21 (44 percent) of the 47 competent subjects consented. Out of the 11 subjects approached by Ratzan (1981), no one gave written consent to the use of sweat patches, urine collection, or venipuncture.

Research is needed at the basic level in the initial stages of subject recruitment to explain the reasons for the reduced participation rates. If the reasons for refusal are known, perhaps modifications or changes can be agreed upon that will enable the elderly subjects to willingly participate in research projects. Otherwise, investigators in their pursuit of larger and more adequate subject populations may be tempted to neglect those research guidelines which have been developed over the last 20 years.

In a project conducted by Robb, Stegman and Wolanin (1986), failure to obtain written, informed consent from the elderly participants was clearly acknowledged. Instead, willingness to participate was obtained by assent, which they define as "the absence of verbal or nonverbal objection to possible participation in a program involving group discussions

of past experiences and answering test questions" (Robb et al., 1986, p. 114). They defend their actions by reporting that the program and study procedures were approved by the human rights committee [undefined] because of the perceived minimal risks identified and also because of the difficulty experienced in locating relatives or guardians. The researchers imply that their study could not have been performed if the rights of the subjects with respect to informed consent had been protected by the researchers and upheld by the human rights committee.

Purpose of the Study

The purpose of this study was to determine which characteristics of elderly nursing home residents influenced the rate of their participation in proposed research.

Research Question

Does the complexity of a research consent form affect the participation rate of elderly nursing home residents in proposed research?

Subsidiary Questions

- 1) Does the education level of elderly nursing home residents affect their participation in proposed research?
- 2) Does the gender of elderly nursing home residents affect their participation in proposed research?
- 3) Does the comprehension ability of elderly nursing home residents affect their participation in proposed research?
- 4) Does the complexity of the consent form affect elderly nursing home residents' comprehension of content in the consent form?

Definition of Terms

- 1) Elderly: individuals who are of an age equal to or greater than 60 years.
- 2) Nursing home: a health care facility for convalescents or infirmed elderly.
- 3) Informed consent: an educated, voluntary act whereby an individual agrees to participate in a research project or action.
- 4) Participant: a person who has signed a written consent form and agrees to take part in a research project.
- 5) Comprehension: the act or capacity to

understand the information presented on a research consent form.

Summary

This chapter has identified a problem that exists in current attempts to involve the institutionalized elderly in research projects. The background information described the events that led up to the current situation and supplied information that helped identify the problem. Data extrapolated from other research reports verified the need for the investigation.

CHAPTER II

REVIEW OF THE LITERATURE

In a recent review of the literature involving studies of elderly subjects, only three were found which identified factors that may influence elderly subjects' participation rates in proposed research. One must keep in mind that in these research projects, the investigators were not mainly or initially studying participation rates of elderly subjects. In fact, the inferences made are perceived correlations extracted from results of data collection methods designed to investigate other problems. As far as this researcher knows, no one has attempted to specifically identify factors that may influence participation rates of institutionalized elderly subjects in proposed research. However, Leader and Neuwirth (1978) have performed a study very similar to the above research proposal involving a model for non-institutionalized elderly subject recruitment.

This chapter reviews the three studies that have identified factors which may influence participation rates of elderly subjects in proposed research. Additional studies that assess significant factors that may influence participation rates of elderly subjects

in proposed research are included. The three studies are as follows; (1) Kelly and McClelland's 1979 study "Signed Consent: Protection or Constraint"; (2) Hoffman, Marron, Fillit and Libow's 1983 study "Obtaining Informed Consent in the Teaching Nursing Home"; and (3) Ratzan's 1981 study "The Experiment That Wasn't: A Case Report in Clinical Geriatric Research."

Review of Significant Studies

In the first study, Kelly and McClelland (1979) suggest that technical language in consent forms and the formality of securing signed consent inhibit elderly subjects' participation rates in proposed research. The purpose of this study was to describe the characteristics of persons in two different post-hospital care settings. However, they contend that one of the incidental findings concerns the difficulty of gathering data from elderly subjects in which obtaining signed consent poses the basic problem. This study revealed that a total of 44 elderly subjects out of the 67 eligible population actually signed the consent forms.

In a teaching nursing home, Hoffman et al. (1983) observed researchers as they attempted to obtain informed consent for clinical research. Out of 38 eligible elderly subjects, two gave written consent for

venipunctures and 24 hour urethral catheterizations. Due to patient reluctance of having 24 hour urethral catheterizations, the researchers modified the project to include straight catheterizations for urine cultures and 8 hour urine collections for renal function studies. With these changes, 7 women gave written consent and 12 more consented to venipunctures and urine collections but refused catheterizations. After modifications, the participating group of subjects who gave written consent involved 55 percent of the original eligible population. Interestingly, Hoffman et al. implied that this report demonstrated how informed consent for clinical research with elderly subjects can be obtained in the teaching nursing home.

In one of the more well-known studies, Ratzan (1981) indicated that out of 312 institutionalized patients none of the 11 subjects who fulfilled criteria for participation gave written consent. The purpose of the study was to evaluate the feasibility of using sweat patches to monitor compliance with digoxin therapy. Subject participation called for the collection of sweat, venipunctures, and urine collection over an eight day period. The researchers performed two interviews with the 11 eligible subjects to ensure they received an adequate amount of information, and to allow the subjects time to reflect

and, if need be, consult with their families and/or physicians.

During the second interview several days later, 10 of the 11 eligible subjects immediately refused to participate. The 11th subject changed her mind on the day the experiment was to begin. Ratzan remarked that the subjects had a marked attitudinal difference between the first and second interview. He contended that three major interactions played a role in the failure to enlist volunteers: (1) subject-experiment, (2) subject-family, and (3) physician-institution.

The subject-experiment interaction probably has the most influence on participation rates. Ratzan proposed that the subjects declined participation because of their fear of discomfort related to venipuncture. The subject-family interaction may affect participation rates due to the paternalistic desire of the families to protect the subjects. However, Ratzan felt that the only interaction that he may be able to influence involves the physician-institution interaction in which the private physician has veto power. In that case he suggested not offering the physician veto power. With all this in mind, Ratzan considers long-term care institutions as not representing ideal or easily workable settings

for performing ethical, non-therapeutic clinical research.

Discussion of Related Studies

In related studies, the major concern identified by researchers was elderly subjects' competency to consent, which Stanley, Guido, Stanley and Shortel (1984) defined as the capacity to comprehend relevant information, the ability to weigh the benefits and risks of proposed research, and the capability to reach a reasonable decision. Some researchers have found no significant difference in elderly subjects' abilities to weigh benefits and risks of research proposals or in their capability to reach a reasonable decision to participate in research when compared with younger subjects (Stanley et al., 1984; Taub, 1980). However, there is a debate in the literature as to whether elderly subjects' capacity to comprehend relevant material is the same as or inferior to their younger counterparts.

Two studies found in the literature imply that age has no effect on the subject's capacity to comprehend content in consent forms. Cassileth, Zupkis, Sutton-Smith and March (1980) utilized a comprehension recall test to ascertain accuracy of subjects' perceptions on the following topics: (1) description

of the treatment, (2) purpose of the treatment, and (3) listing of a major risk or complication. No significant differences were found when comparing comprehension test scores within each of the following categories: gender, age, race, and treatment. However, comprehension scores reflected a direct correlation with education levels of those same subjects.

In the other study Goodman, Cooper, Malins and Prys-Roberts (1984) also suggested that the age of the subject had no effect on comprehension. The researchers developed a questionnaire containing three blocks of questions to determine comprehension levels. The first block of questions inquired about the subjects' pre-operative visit. The second block of questions dealt with the subjects' operation experience. The final block of questions covered the subjects' post-operative day. This particular questionnaire, which encompassed many aspects of the research project, may not specifically represent subjects' comprehension of content in the consent forms.

On the other hand, in the literature reviewed, many of the investigators proclaimed a significant and inverse correlation between elderly subjects' comprehension abilities and their age. These

investigators agreed that advanced age influences elderly subjects' ability to comprehend but frequently cited different age associated factors as the causal component.

Some investigators suggested that the relationship between the natural aging process and the elderly population's higher percentage of impaired physical attributes, such as loss of hearing and poor vision, contributes to the lower comprehension levels cited in research reports which compare the young and old (Berkowitz, 1978; Hoffman et al., 1983). The investigators often found follow-up visits or a two or three part consent process necessary to reinforce the content of the original discussion. It would be misleading to imply that these researchers only discussed physical attributes of elderly subjects in their reports concerning comprehension.

There are others who propose that the lower comprehension levels correlate with impaired psychological aspects which also are more prevalent in the elderly population. These investigators reported reductions in short term memory, possibly related to inadequate information acquisition (Craik & Masani, 1967; Taub, 1979), a less flexible style of information retrieval (Ceci & Tabor, 1981), or latent dementia, especially dementia of the Alzheimer's type (Ratzan,

1980) as the contributing agent for elderly subjects' inability to comprehend normally. These inherent physiological and psychological attributes of the elderly may not be the sole contributors to the total etiology of the reduction in elderly subjects' ability to comprehend.

As previously alluded to, comprehension levels reflect a direct correlation with education levels of elderly subjects (Cassileth et al., 1980; Taub, Baker & Sturr, 1986). Taub et al. (1986) speculated that while ensuring informed consent may be difficult for all volunteers, it may be a critical problem for elderly subjects with less education. Interestingly, memory for informed consent materials does not differ for young and elderly adults who possess high education levels and vocabulary abilities.

Another factor that may influence comprehension of elderly subjects involves the readability of informed consent forms. Two independent studies by Grunder (1980) and Marrow (1980) both used the Fry readability scale and the Flesch readability formula to ascertain readability levels of consent forms. In Grunder's study five consent forms were collected from five different hospitals in which the above tests indicated a minimum requirement of college level reading skills to comprehend the forms' content. The same type of

results were obtained in Marrow's project involving 60 consent forms from five national cancer clinical trial groups. He insisted that the consent forms' content was slightly less difficult to comprehend than medical journals. Three out of every four passages in the consent forms required a college level or greater reading ability to comprehend. These studies did not measure comprehension. Therefore, any projections estimating possible comprehension level scores would be purely speculative.

In a study that measured comprehension levels of two identical consent forms differing only in readability difficulty, one at the seventh grade level and the other at the college level, Taub et al. (1986) found no consistent results. They continued to suggest that simplifications of consent forms accomplished by reducing the number of syllables per word and words per sentence, may not, by itself, be sufficient to improve comprehension. However, they also stated that in view of the lack of consistent findings, future research is necessary to further explore potential effects of readability on comprehension.

Summary

This chapter reviewed three studies that identified factors which may influence participation rates of elderly subjects in proposed research. Even though the researchers reported participation rates, the studies were not designed for this purpose.

The chapter also discussed other popular studies in which the researchers identified factors that may influence participation rates of elderly subjects in proposed research. The majority of these studies sought to determine competency by measuring subject comprehension of content in the consent forms. Two researchers implied that age did not affect comprehension. However, many other researchers found a significant decrease in comprehension as the age of the subject increased. The investigators disagree as to exactly which causal factors inhibit the elderly subjects' comprehension ability.

CHAPTER III

METHODS

Study Design

A quasi-experimental design was utilized in this study. Participation or non-participation in this research project represented the dependent variable. If the subject signed the consent form, participation was signified. The independent variable was the presentation of a simple or complex consent form to the subject.

Subject Description

In this study "elderly nursing home residents" referred to a population of people living in nursing homes who at the time of data collection were 60 years of age or older. The selected population resided at either the Knoxville Health Care Center (KHCC) or Hillcrest West (HCW), both of which are located in Knoxville, Tennessee. Of this population, only those individuals assessed with mild or no intellectual impairment by the modified Short Portable Mental Status Questionnaire (SPMSQ) were eligible for inclusion in the study.

The HCW nursing home presented a list of 55 potentially eligible subjects out of the total population of 177. Of the 55 potentially eligible subjects, 19 presented with moderate or severe intellectual impairment, and 36 with mild or no intellectual impairment as ascertained by the modified SPMSQ.

The KHCC nursing home also provided a list containing 52 potentially eligible subjects chosen from the total population of 170. Out of the 52 potentially eligible subjects, 18 presented with moderate or severe intellectual impairment, and 32 with mild or no intellectual impairment as ascertained by the modified SPMSQ. However, two of the latter subjects were discharged prior to the second researcher-subject contact. See figure 2-1 for an accumulated categorization of the 66 eligible subjects with no intellectual impairment and mild intellectual impairment.

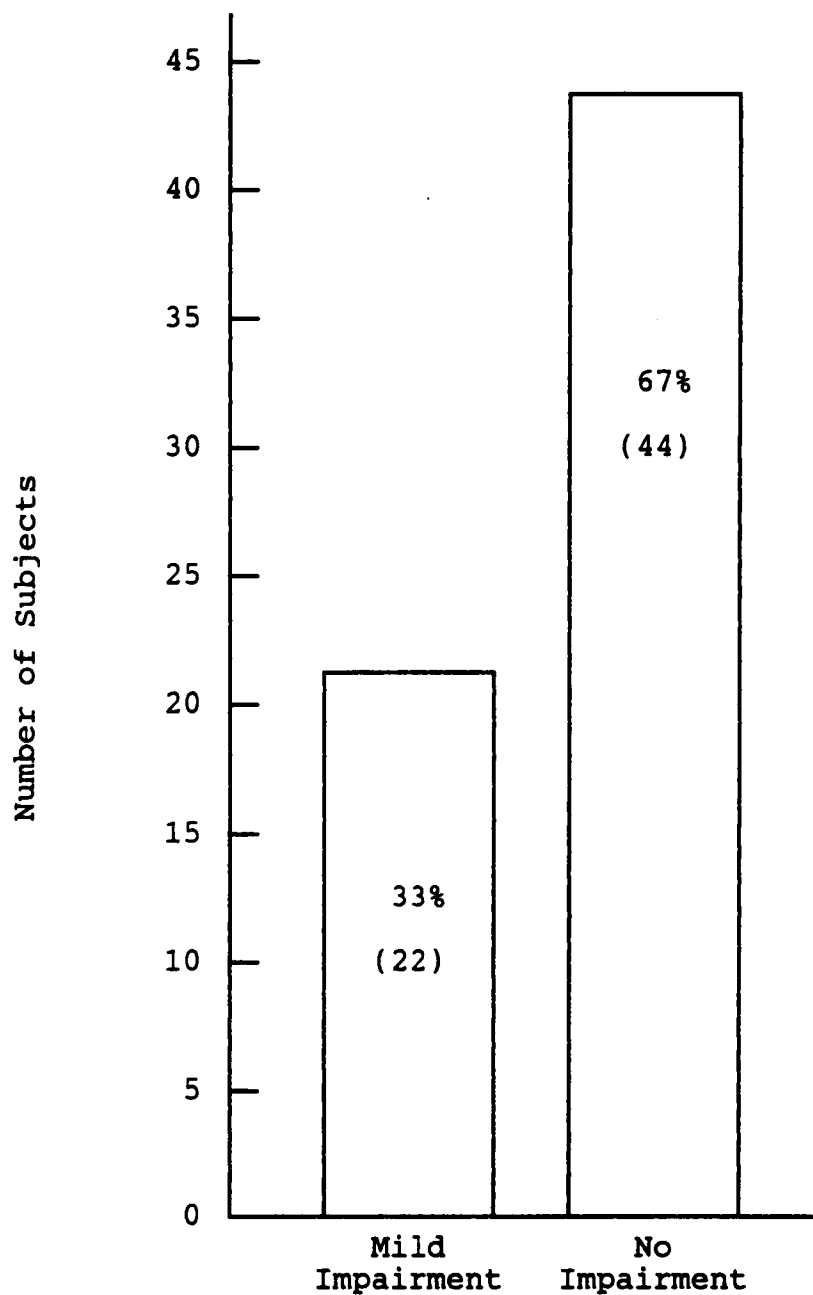


Figure 2-1. Sixty-six subjects' intellectual status.

Mental Status Test

In a study by Williams, Campbell, Raynor, Musholt, Mlynarczyk, and Crane (1985), the mental status questionnaire score presented as the most important predictor of cognitive impairment. The SPMSQ, a 10 item test developed by Pfeiffer (1975), is one of the most frequently used mental status questionnaires. The SPMSQ was administered verbally to a number of elderly nursing home residents. It was discovered early during data collection that a modification involving the deletion of one of the SPMSQ questions would be necessary. Question number 4 "What is your telephone number?" proved inappropriate, since the subjects participating in this study were not provided telephones by the nursing homes where they reside. This modified SPMSQ was utilized to classify the subjects into intellectual capability levels identified as intact, mild intellectual impairment, moderate intellectual impairment, and severe intellectual impairment.

To avoid sight and hearing problems the researcher verbally asked the questions contained in the modified SPMSQ. The answers were recorded by the researcher on an appropriately coded SPMSQ form. The modified SPMSQ form may be seen in appendix A.

Other mental status questionnaires with greater reliability and/or validity could have been used, but they were more complex and contained a larger number of questions. Foreman (1987) compared three mental status questionnaires and found the SPMSQ to have an internal consistency of .897 which implies that it did measure just one attribute. The criterion related validity for the SPMSQ measured by a Spearman correlation with the other tests equaled .71 ($P < .001$). Foreman concluded that the various parameters of reliability and validity were relatively consistent within and across the three questionnaires that he compared.

Consent Forms

Simple and complex consent forms were written at the sixth grade and college levels respectively, as ascertained by the Fry Readability Scale (Fry, 1968). The two consent forms contained the same amount and type of information; only the written level of complexity differed.

The complex consent form seen in appendix B is a modification by the researcher of a standard consent form developed by John S. Jozwiak, a professor at the University of Tennessee in Knoxville. The simple consent form seen in appendix C evolved from the content of the complex form. Without changing the

basic format or eliminating any main points of information, the simple consent form was rewritten in more easily understood language accomplished by eliminating unnecessary phrases and words, shortening sentences, and by using simpler words in place of more technical ones. To illustrate these changes, a comparison can be made between the complex consent form statement "you are invited to participate in a research study designed to identify specific factors of the nursing home resident which may reveal intrinsic commonalities useful in the development of more efficient long term care" and the simple consent form statements "would you like to be in a research study? This study will find out what people in nursing homes have in common." Again the differences can be seen between the complex consent form statement "your participation will involve two venipuncture procedures extracting no more than 10 ml. of blood" and the simple consent form statement "if you sign this form, 2 teaspoons of blood will be drawn by a needle from your arm."

Comprehension Test

The researcher developed a comprehension test to ascertain the subjects' understanding of the information contained in the consent forms. The

comprehension test consisted of five multiple choice questions that made inquiries about pertinent information contained in the simple and complex consent forms. The comprehension test may be seen in appendix D.

Procedures

Three nursing homes were approached by the researcher to gain access to the residents. The nursing home administrators at KHCC and HCW agreed to allow the researcher to initiate a proposed research study in their facilities. Copies of the permission letters were filed at the University of Tennessee, Knoxville along with the form A research approval.

Consultation with health care personnel at each nursing home was initiated to obtain a list of potentially eligible subjects with adequate intellectual capabilities. The researcher procured a list of these individuals and identified them only by room number. Initial contact with those potentially eligible individuals was then made.

After introductions had taken place, the researcher asked the subjects for permission to conduct an interview. If permission was given, individual verbal testing was administered using the SPMSQ until an adequate number of eligible subjects was attained.

Subjects identified as eligible were those individuals having mild or no intellectual impairments as assessed by the SPMSQ.

Result sheets for the SPMSQ contained only demographic information not individual names. The subject's room number was used for identification purposes. In order to utilize a random number table to assign the eligible subjects a simple or complex consent form, the subjects' room numbers were listed on a separate sheet of paper and numbered consecutively 1,2,3... until each room number had been identified with a number label. The total number of eligible subjects was divided by two which resulted in two equal numbers of 34. The researcher used a random number table to select 34 eligible subjects to make up one group of eligible subjects. The remaining 34 eligible subjects made up the second group. A quarter was flipped to determine which group would receive a simple consent form and which group would receive a complex consent form. The listed room numbers were then coded "S" for simple consent forms or "C" for complex forms.

The next step involved individual contact of the researcher with 5 to 10 eligible subjects each day. The researcher read aloud to each subject, compensating for any sight or hearing discrepancies, the consent form previously assigned to him or her. The consent

form was then handed to the subject for perusal and possible signing. Any questions posed by the subject about the study were answered according to the criteria identified in the consent form.

The researcher then accepted the signed or unsigned consent form followed immediately by a verbally administered comprehension test to check for any memory deficits. The subjects' responses were recorded on an appropriately numbered test form. The test identified the percentage of the consent form information comprehended by the subject. The subject was informed that another contact would be made in approximately three to four weeks.

This procedure was repeated with each subject as long as time allowed until the required quota of clients was obtained. A final individual meeting was initiated to debrief the subjects as to exactly what their participation in the study involved. They were informed that no venipunctures would be performed and that the researcher was investigating the reasons why elderly nursing home residents are reluctant to participate in research projects. Any of the subjects' questions and/or concerns were then addressed.

Researcher's Hypothesis

The researcher hypothesized that elderly nursing home residents who receive a simple consent form would participate in proposed research in greater number than elderly nursing home residents who receive a complex consent form. The researcher suspected that the elderly subjects would more readily participate in a project in which they had a greater understanding of the procedures. The researcher speculated that the simple consent form would allow the subject a greater understanding of the procedures.

Summary

This chapter identified the following components of the research project: (1) Study design, (2) Subject description, (3) Mental status test, (4) Consent forms, (5) Comprehension test, (6) Procedures, and (7) Researcher's hypothesis. A quasi-experimental design was utilized in this study. The dependent variable involved participation status and the independent variable included the presentation of consent forms written at different complexity levels.

The subjects were people age 60 years and older and reside at KHCC or HCW nursing homes. A modified version of the SPMSQ was used to detect intellectual impairment. Consent forms differing only in complexity

were assigned and presented to eligible subjects. A comprehension test was verbally administered immediately after accepting the consent form.

In the final section, the researcher presented a hypothesis drawn from information in the preceding literature review chapter. This hypothesis has been tested and will be accepted or rejected in chapter V in accordance with the findings in chapter IV.

CHAPTER IV

RESULTS

The researcher was able to accumulate data pertaining to the 66 eligible subjects from the procedures implemented while performing the research project. The primary results were extrapolated from the following relationship comparisons:

- (1) Complexity/Participation
- (2) Education/Participation
- (3) Gender/Participation
- (4) Comprehension/ Participation
- (5) Complexity/Comprehension

The relationship comparisons correspond with the following questions respectively: (1) Research question, (2) Subsidiary question one, (3) Subsidiary question two, (4) Subsidiary question three, and (5) Subsidiary question four. The discussion that follows provides a descriptive and inferential analysis of the primary data. Due to the nominal level of the data, chi-square was used for all inferential analyses.

Research Question

The researcher inquired as to whether or not the complexity of a research consent form affects the participation rate of elderly nursing home residents in proposed research. The results seen in table 4-1 are appropriately categorized according to the research question. There was an equal distribution of simple and complex forms initially, however, two of the subjects who received a simple form were discharged. The computed chi-square with 66 subjects and $df=1$ resulted in 4.793 significant at the .05 level.

Table 4-1

Contingency table Complexity/Participation relationship

	<u>Simple Form</u>		<u>Complex Form</u>		<u>Total</u>
	<u>Expected</u>	<u>Observed</u>	<u>Expected</u>	<u>Observed</u>	
Signed	(11.27)	7	(12.73)	17	24
Unsigned	(19.73)	<u>24</u>	(22.27)	<u>18</u>	<u>42</u>
<u>Totals</u>		31		35	66

Subsidiary Question One

In the first subsidiary question, the researcher dealt with the relationship between nursing home residents' education level and their participation in proposed research. Table 4-2 presents the relationship of subjects having less than or equal to an eighth grade education, or greater than an eighth grade education as pertaining to their participation in proposed research. The obtained chi-square, which equals .385, $df=1$, was not significant when applied to the data collected from the 66 subjects. Figure 4-1 illustrates the educational level distribution of the subject population from third grade to college level.

Table 4-2

Contingency table Education/Participation relationship

	<u>≤ Eighth Grade</u>		<u>≥ Ninth Grade</u>		<u>Total</u>
	<u>Expected</u>	<u>Observed</u>	<u>Expected</u>	<u>Observed</u>	
Signed	(12.20)	11	(10.80)	12	23
Unsigned	(22.80)	<u>24</u>	(20.20)	<u>19</u>	<u>43</u>
Totals		35		31	66

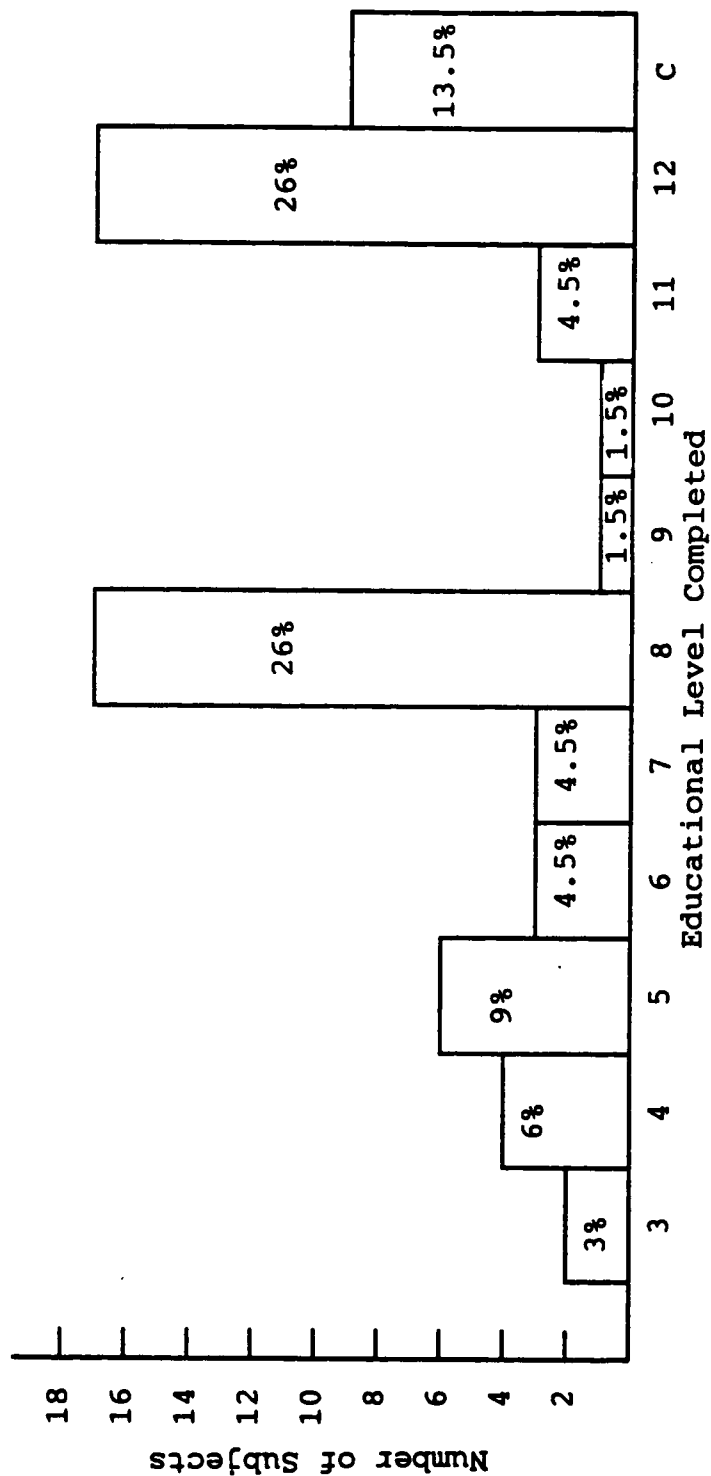


Figure 4-1. Sixty-six subjects' educational level.

Subsidiary Question Two

In the second subsidiary question, the researcher inquired as to the possible influence gender might have on elderly nursing home residents' participation in proposed research. Table 4-3 presents the relationship between the subjects' gender and their participation in proposed research. The female subjects outnumber the male subjects two to one as shown in figure 4-2. The computed chi-square with 66 subjects and $df=1$ resulted in a nonsignificant .295.

Table 4-3

Contingency table Gender/Participation relationship

	<u>Male</u>		<u>Female</u>		<u>Total</u>
	<u>Expected</u>	<u>Observed</u>	<u>Expected</u>	<u>Observed</u>	
Signed	(8)	7	(16)	17	24
Unsigned	(14)	<u>15</u>	(28)	<u>27</u>	<u>42</u>
<u>Totals</u>		22		44	66

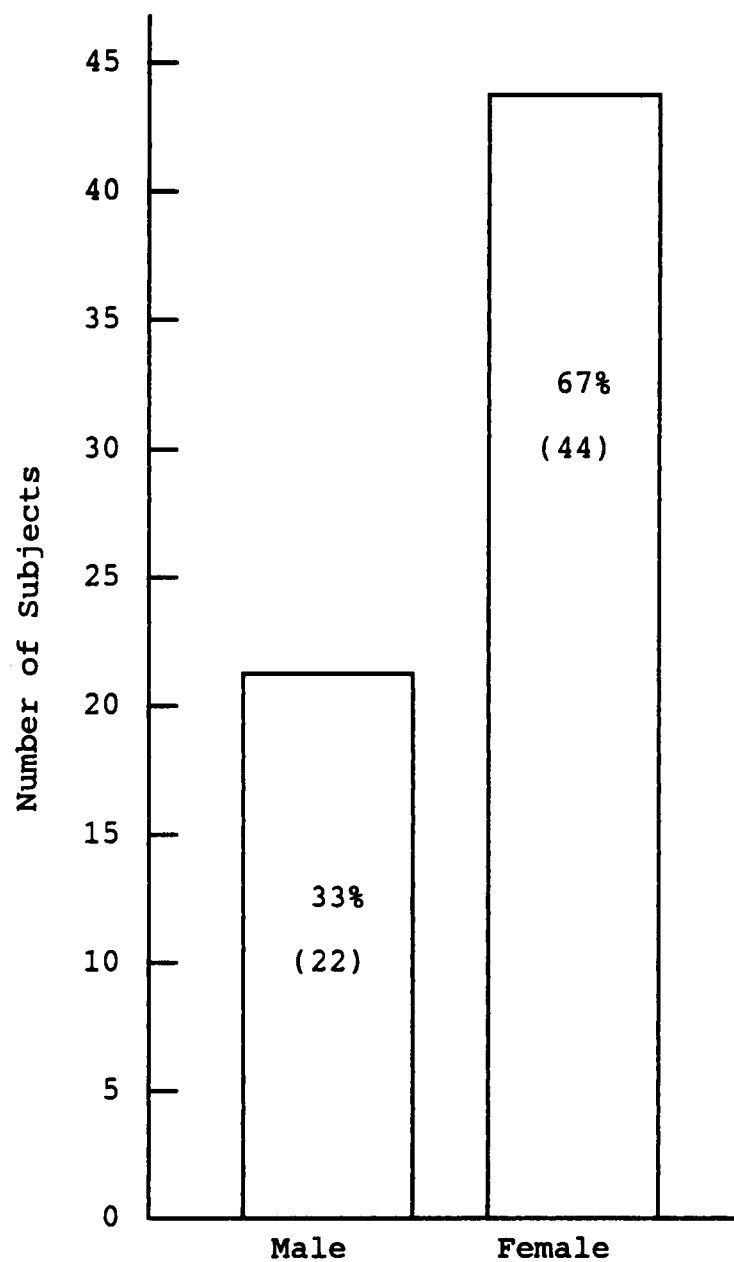


Figure 4-2. Sixty-six subjects' gender.

Subsidiary Question Three

The third subsidiary question entailed the relationship of elderly nursing home residents' correct responses on a five question multiple choice comprehension questionnaire and their participation in proposed research. Table 4-4 relates participation in proposed research with two category groups:

- (1) subjects with two or less correct responses, and
- (2) subjects with three or more correct responses.

Figure 4-3 depicts percentage distribution of the subjects, categorized according to the number of correct responses. The total number of subjects equaled only 61 because five of the subjects who decided not to participate also refused to take the comprehension test. The obtained chi-square which equaled 1.431, $df=1$, was not significant.

Table 4-4

Contingency table Comprehend/Participation relationship

	<u>≤ 2 Correct</u>		<u>≥ 3 Correct</u>		<u>Total</u>
	<u>Expected</u>	<u>Observed</u>	<u>Expected</u>	<u>Observed</u>	
Signed	(7.08)	5	(16.92)	19	24
Unsigned	(10.92)	<u>13</u>	(26.08)	<u>24</u>	<u>37</u>
<u>Totals</u>		18		43	61

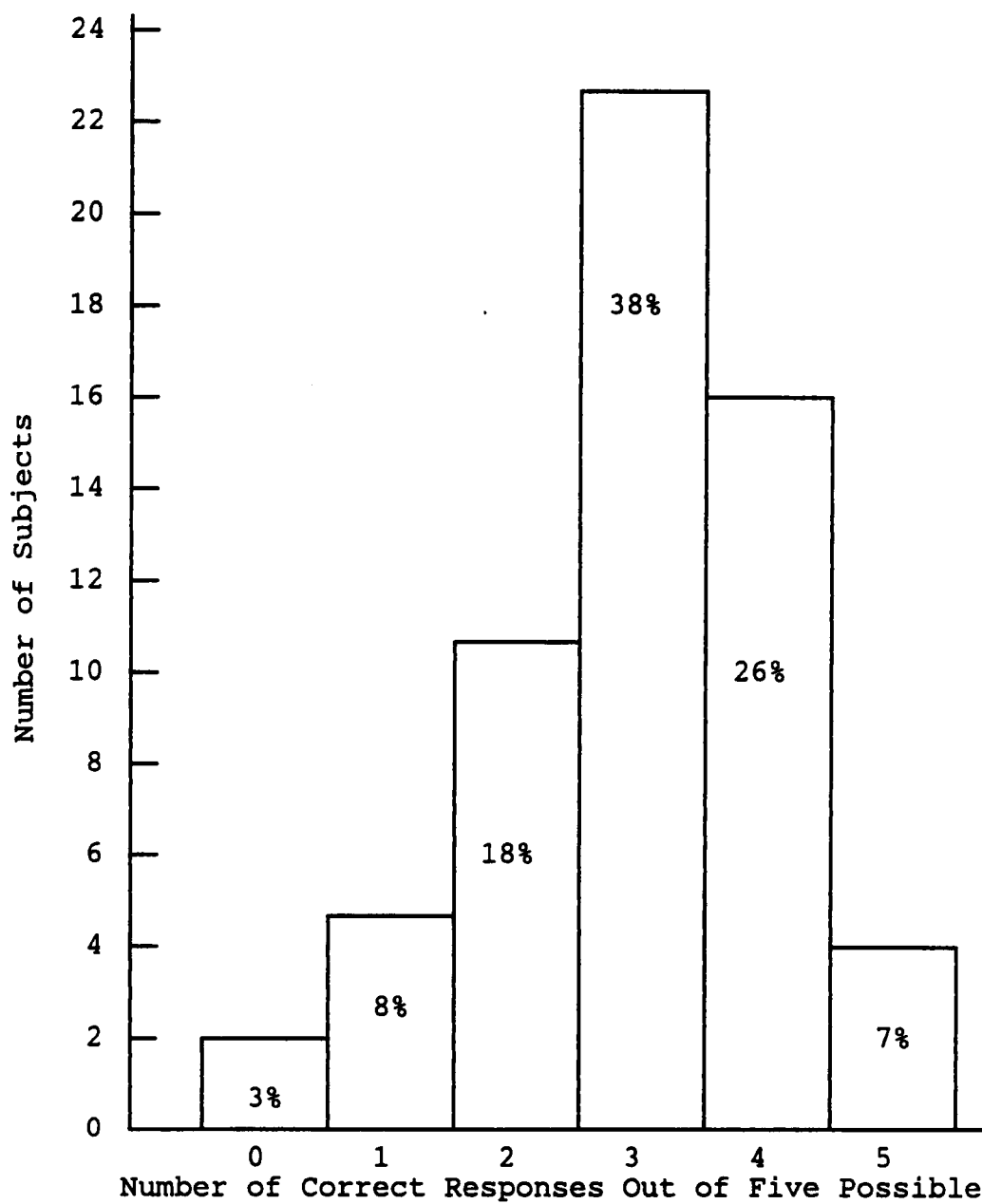


Figure 4-3. Sixty-one subjects' correct responses.

Subsidiary Question Four

In the final subsidiary question, the researcher explored the relationship between the complexity of the consent form and its effect on elderly nursing home residents' comprehension of the consent form content. Table 4-5 displays this relationship. The calculated chi-square with 61 subjects and $df=1$ resulted in a nonsignificant .000. Figure 4-4 illustrates the number of subjects who received a simple consent form compared with the number of correct responses they gave on the comprehension test. Figure 4-5 presents the number of subjects who received a complex form compared with the number of correct responses they gave on the comprehension test. As mentioned previously, five of the subjects who decided not to participate also refused to take the comprehension test.

Table 4-5

Contingency table Complexity/Comprehend relationship

	<u>Simple</u>		<u>Complex</u>		<u>Total</u>
	<u>Expected</u>	<u>Observed</u>	<u>Expected</u>	<u>Observed</u>	
≤ 2 CR*	(7.97)	8	(10.03)	10	18
≥ 3 CR*	(19.03)	<u>19</u>	(23.97)	<u>24</u>	<u>43</u>
<u>Totals</u>		27		34	61

* CR= correct responses.

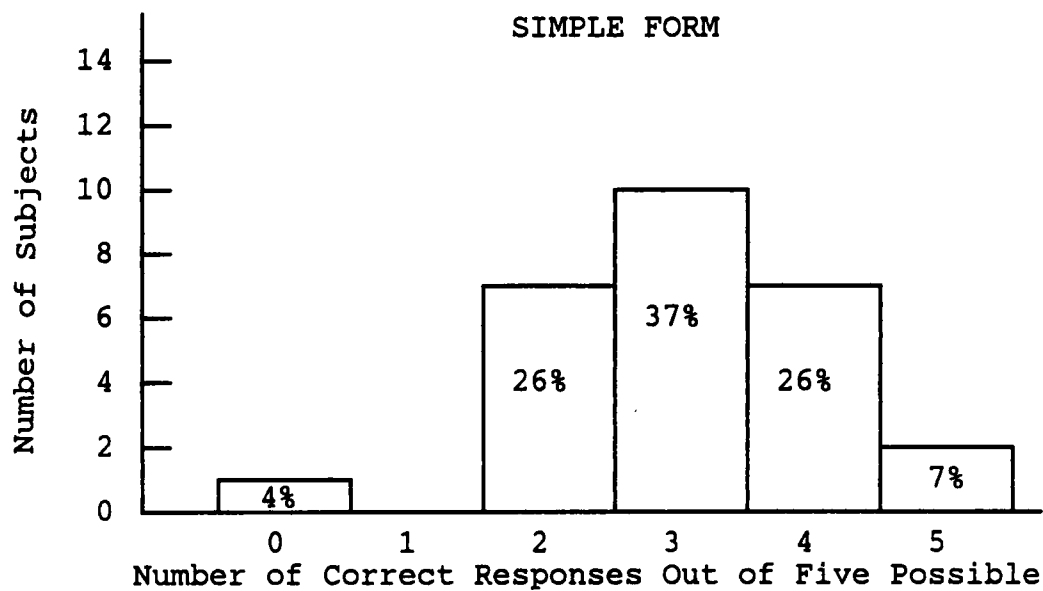


Figure 4-4. Twenty-seven subjects' correct responses with simple consent forms.

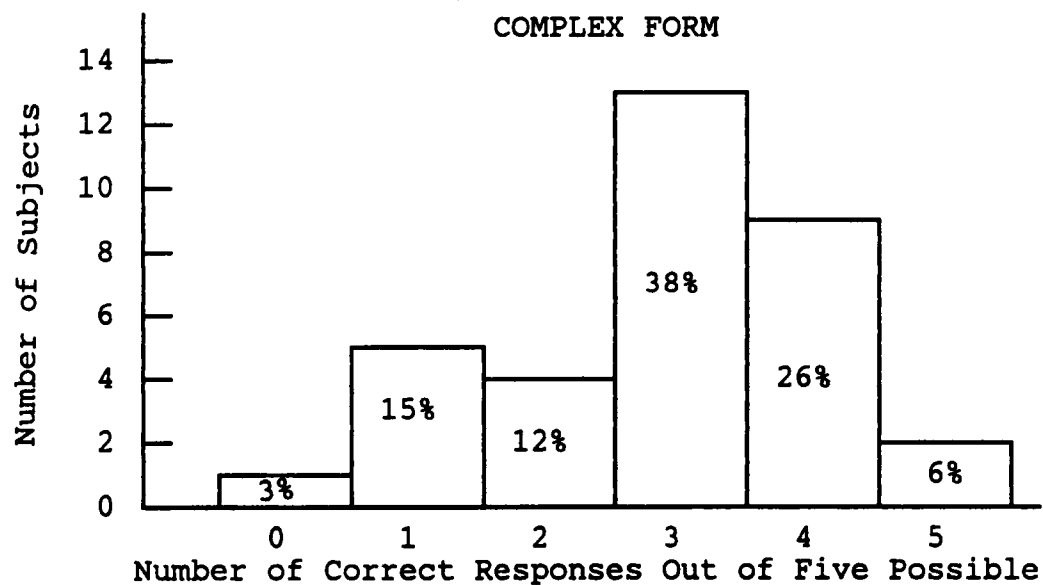


Figure 4-5. Thirty-four subjects' correct responses with complex consent forms.

Summary

Of the five comparisons, there was only one statistically significant finding. Table 4-6 represents a summary of the category comparisons and appropriate questions with resultant chi-squares.

Table 4-6

Question related comparison table with χ^2 results

Questions	Comparison Categories	χ^2
Research	Complexity/Participation	4.793*
Subsidiary One	Education/Participation	.385
Subsidiary Two	Gender/Participation	.295
Subsidiary Three	Comprehend/Participation	1.431
Subsidiary Four	Complexity/Comprehend	.000

* $P < .05$, $df=1$, significant $\chi^2 = 3.84$

This chapter presented five comparisons of research project results. The five comparisons reflected results that correlate to the following questions: (1) Research question, (2) Subsidiary question one, (3) Subsidiary question two, (4) Subsidiary question three, and (5) Subsidiary question four. Only one comparison, complexity/participation appeared to differ significantly. The obtained

chi-square equals 4.793, $df=1$, which was significant at the .05 level.

CHAPTER V

DISCUSSION

This chapter contains the researcher's inferences and speculations drawn from the results in chapter IV. The proceeding discussion covers the following topics: (1) Discussion of hypothesis, (2) Discussion of results, (3) Limitations of the study, and (4) Recommendations for future research.

Discussion of Hypothesis

The hypothesis that elderly nursing home residents who receive a simple consent form will agree to participate in proposed research in greater numbers than those who receive a complex form was rejected. This result was exactly opposite to that anticipated by the researcher.

Discussion of Results

A discussion of the results for the research question and each subsidiary question is presented in the following section. This discussion includes a summary of the findings, and the researcher's interpretations and conclusions.

The research question involved a comparison of participation rates of elderly nursing home residents when given either a complex or simple consent form. The results were significant at the .05 level which suggests that this would not occur by chance 95 percent of the time. As alluded to in the discussion of hypothesis section, the elderly nursing home resident signed the complex form in greater numbers than the simple form.

It would be reasonable to postulate that the difference may be partly attributable to the subjects' education level. However, the relationship of education levels and participation rates of elderly nursing home residents was not found to be statistically significant. Of interest, Taub et al. (1986) found education levels significantly and positively correlated to comprehension. With this in mind, one might suspect that like education, levels of comprehension would have no influence on participation.

As suspected, the influence that comprehension has on participation was found nonsignificant. This surprised the researcher who hypothesized that the subjects would sign the simple consent form in greater numbers perhaps due to an increased comprehension of the consent form content. However, not only did the subjects sign the complex form in greater numbers,

their level of comprehension had no effect on participation.

The relationship between complexity of consent forms and subject comprehension levels was not significant. This result supports Taub et al's. (1986) inconsistent findings related to comprehension and consent form complexity. However, Grunder's (1980) and Marrow's (1980) notions that a more simply written consent form will allow greater comprehension were not supported in this study.

The apparent nonsignificant difference found when comparing gender and participation was not surprising. The researcher felt obligated to test for significance between gender and participation only because the investigation involved such a new research concept.

Summary

It is unclear why the elderly subjects signed the complex consent form in greater numbers. However, the researcher suspects that the subjects may have had preconceived ideas in which the complex form fit their expectations for a research project and therefore responded accordingly by signing the form. The language used on the complex form may have been similar to that used by their physicians and other authority figures; reluctance to question authority may be evident in this primarily female elderly sample.

Limitations of the Study

The inferential results obtained in this study are not generalizable to all nursing homes and should be interpreted with caution. The two facilities, KHCC and HCW, are not restricted to private pay. Also, the facilities are both located in the same city with the same environmental and social stressors.

Out of the total combined population of 347 residents in both nursing homes, only 66 presented with mild or no intellectual impairment. One must assume that all of the subjects not deemed eligible by the nursing homes' health care personnel would have obtained a moderate or severe intellectual impairment rating.

Even though this project contained a comprehension test, the researcher feels that it did not adequately test all aspects of comprehension. The comprehension test was developed by the researcher and only contained five multiple choice questions. Researchers, whose investigations primarily concentrate on comprehension, usually use a longer test consisting of subjective and objective questions to obtain greater insight (Silva & Sorrell, 1984; Taub & Baker, 1984).

Recommendations for Future Research

A replication of this study is needed to determine reliability and validity of the comprehension test and the procedures used.

A project patterned after this study using subjects residing at private nursing homes or a mixture of the two is needed. The geographic region may also be a factor which effects participation.

This study dealt with a hypothetical treatment of venipuncture. Studies inquiring about the effects of consent form complexity on participation with different levels of treatment invasiveness are needed.

The researcher in this project wore exactly the same clothes; white shirt, tie, slacks, and a white lab coat. A study focusing on how the researcher effects participation where a comparison of differences in age, wardrobe, and/or gender could be performed.

LIST OF REFERENCES

REFERENCES

- Appelbaum, S., & Roth, H. (1982). Competency to consent to research: A psychiatric overview. Archives of General Psychiatry, 39, 951-958.
- Baker, T., & Taub, A. (1983). Readability of informed consent forms for research in a veterans administration medical center. The Journal of the American Medical Association, 250 (19), 2646-2648.
- Berkowitz, S. (1978). Informed consent, research, and the elderly. The Gerontologist, 18 (3), 237-243.
- Butler, N. (1981). The teaching nursing home. The Journal of the American Medical Association, 245 (14), 1435-1437.
- Cassidy R., & Oddi, F. (1986). Legal and ethical aspects of informed consent: A nursing research perspective. Journal of Professional Nursing, 2, 343-349.
- Cassileth, R., Zupkis, V., Sutton-Smith, K., & March, V. (1980). Informed consent: Why are its goals imperfectly realized? The New England Journal of Medicine, 302 (16), 896-900.
- Ceci, J., & Tabor, L. (1981). Flexibility and memory: Are the elderly really less flexible? Experimental Aging Research, 7 (20), 147-158.

- Craik, F., & Masani, P. (1967). Age differences in the temporal integration of language. British Journal of Psychology, (58), 291-299.
- Foreman, D. (1987). Reliability and validity of mental status questionnaires in elderly hospitalized patients. Nursing Research 36 (4), 216-220.
- Freeland, M., Calat, G., & Schedler, C. (1980). Projections of national health expenditures, 1980, 1985, and 1990. Health Care Financing Review, 1, 1-27.
- Fry, E. (1968). A readability formula that saves time. Journal of Reading, 11, 513-516; 575-578.
- Goodman, N., Cooper, G., Malins, A., & Prys-Roberts, C. (1984). The validity of informed consent in a clinical study. Anaesthesia, 39, 911-916.
- Grunder, T. (1980). On the readability of surgical consent forms. The New England Journal of Medicine, 302 (16), 900-902.
- Hoffman, B., Marron, R., Fillit, H., & Libow, S. (1983). Obtaining informed consent in the teaching nursing home. Journal of the American Geriatrics Society, 31 (9), 565-569.
- Kelly, K., & McClelland, E. (1979). Signed consent: Protection or constraint? Nursing Outlook, 10 (1), 40-42.

- Leader, A., & Neuwirth, E. (1978). Clinical research and the noninstitutional elderly: A model for subject recruitment. Journal of the American Geriatrics Society, 26 (1), 27-31.
- Makarushka, L., & McDonald, D. (1979). Informed consent, research, and geriatric patients: The responsibility of institutional review committees. The Gerontologist, 19 (1), 61-66.
- Morrow, R. (1980). How readable are subject consent forms? Journal of the American Medical Association, 244 (1), 56-58.
- Pfeiffer, E. (1975). A short portable mental status questionnaire for the assessment of organic brain deficit in elderly patients. Journal of the American Geriatrics Society, 23, 433-441.
- Ratzan, M. (1980). Being old makes you different: The ethics of research with elderly subjects. Hastings Center Report, 10, 32-42.
- Ratzan, M. (1981). The experiment that wasn't: A case report in clinical geriatric research. The Gerontologist, 21 (3), 297-302.
- Reich, T. (1978). Ethical issues related to research involving elderly subjects. The Gerontologist, 18 (4), 326-337.

- Robb, S., Stegman, E., & Wolanin, O. (1986). No research versus research with compromised results: A study of validation therapy. Nursing Research, 35 (2), 113-117.
- Silva, M., & Sorrell, J. (1984). Factors influencing comprehension of information for informed consent: Ethical implications for nursing research. International Journal of Nursing Studies, 21 (4), 233-240.
- Stanley, B., Guido, J., Stanley, M., & Shortell, D. (1984). The elderly patient and informed consent: Empirical findings. Journal of the American Medical Association, 252 (10), 1302-1306.
- Steinberg, A., Fitten, J., & Kachuck, N. (1986). Patient participation in treatment decision-making in the nursing home: The issue of competence. The Gerontologist, 26 (4), 362-365.
- Stuart, B. (1978). Protection of the right to informed consent to participate in research. Behavior Therapy, 9, 73-82.
- Taub, H. (1979). Comprehension and memory of prose materials by young and old adults. Experimental Aging Research, 5 (1), 3-13.

- Taub, H. (1980). Informed consent, memory and age. The Gerontologist, 20 (6), 686-690.
- Taub, H., Baker, T., & Sturr, F. (1986). Informed consent for research: Effects of readability, patient age, and education. Journal of the American Geriatric Society, 34 (8), 601-606.
- Taub, H., & Baker, M. (1984). A reevaluation of informed consent in the elderly: A method for improving comprehension through direct testing. Clinical Research, 32 (17), 17-21.
- Watson, B. (1982). Informed consent of special subjects. Nursing Research, 31 (1), 43-47.
- Williams, M., Campbell, E., Raynor, W., Musholt, M., Mlynarczyk, S., & Crane, L. (1985). Predictors of acute confusional states in hospitalized elderly patients. Research in Nursing & Health, 8, 31-40.
- U.S. Bureau of Census. (1986). Statistical abstract of the United States: 1987 (107th ed.). Washington, DC: Author.

APPENDIXES

APPENDIX A
MODIFIED (SPMSQ)

Eligible () Not Eligible () Room # ()
 Gender: M F Race: Caucasian Black Other

Short Portable Mental Status Questionnaire (SPMSQ)

- | <u>No-Yes</u> | <u>Pertinent Questions</u> |
|---------------|---|
| N Y | 1. What is the date today? ____/____/____ |
| N Y | 2. What day of the week is it? _____ |
| N Y | 3. What is the name of this place? _____ |
| N Y | 4. How old are you? ____ |
| N Y | 5. When were you born? ____/____/____ |
| N Y | 6. Who is the current president of the United States?
_____ |
| N Y | 7. Who was the president just before him?
_____ |
| N Y | 8. What was your mother's maiden name?
_____ |
| N Y | 9. Subtract 3 from 20 and keep subtracting 3 from
==== each new number all the way down.
cross out 20, 17, 14, 11, 8, 5, 2. |

Total Errors _____

() Subtract one error if subjects had no grade school - _____

() Add one error if subject has had above high school + _____

Final Error Score _____

() 0-2 errors = intact

() 3-4 errors = mild intellectual impairment

() 5-7 errors = moderate intellectual impairment

() 8-10 errors = severe intellectual impairment

Source: After Duke University Center for the Study of Aging
and Human Development, 1978.

APPENDIX B
COMPLEX CONSENT FORM

Room # ()

The University of Tennessee, Knoxville
College of Nursing
1200 Volunteer Boulevard
Knoxville, Tennessee 37996-4110
Telephone (615) 974-4151

Dear Resident:

You are invited to participate in a research study designed to identify specific factors of the nursing home resident which may reveal intrinsic commonalities useful in the development of more efficient long term care. Your participation will involve two venipuncture procedures extracting no more than 10 ml. of blood. The actual procedures, taking less than 10 minutes each, will be separated by an approximate time span of 6 weeks. A verbal comprehension test will be administered prior to any of the actual procedures.

No negative effects are expected to result from your participation in the project. Although no positive effects are guaranteed, you can receive information about your body functions that potentially could have long-term health benefits.

All data will be kept confidential and stored in a locked filing cabinet in the researcher's home. Each form will be coded with an identification number. Only the researcher will be able to identify individual respondents. All data will be summarized for any presentations or publications that arise from the research.

Participation in this project is voluntary and your consent for participation may be withdrawn at any time prior to completion of the data analysis by giving written notice to the researcher listed below. There is no penalty for withdrawal from the project.

If you have any questions about your participation in the study, please feel free to contact the researcher listed below.

I have read and understand the above statements. I freely consent to participate in this project under the above conditions. Please include your address only if you would like a report of what your responses indicate.

Signed _____
Date _____
Address _____

Douglas H. Walters
588-3422

APPENDIX C
SIMPLE CONSENT FORM

Room # ()

The University of Tennessee, Knoxville
College of Nursing
1200 Volunteer Boulevard
Knoxville, Tennessee 37996-4110
Telephone (615) 974-4151

Dear Resident:

Would you like to be in a research study? This study will find out what people in nursing homes have in common. An increase in long-term health benefits may result from these findings.

If you sign this form, 2 teaspoons of blood will be drawn by a needle from your arm. It will take less than 10 minutes to draw the blood. A second drawing will be done 6 weeks after the first. Before this, you will take a test to show how much you know about this study.

No negative effects are expected to result if you take part in this project. Although no positive effects are guaranteed, you can ask for a copy of the results. This could possibly increase long-term health benefits.

The data will be kept in a locked drawer at the researcher's home. Your name will not be on the forms. The researcher will be the only one who knows which form is yours. Your data will be mixed with all the other data. Only the main results will be told.

You can choose whether or not you want to take part in this study. Your care will not change if you drop out or choose not to be in the study. Just tell the researcher if you want to drop out. You do not have to sign this form if you do not want to take part in the study.

If you have any questions about the study, please feel free to contact the researcher listed below.

I have read this form and I know what it means. I want to be a part of this study, and I will do only what I read above. I will fill in my address only if I want a copy of the results.

Signed _____
Date _____
Address _____

Douglas H. Walters
588-3422.

APPENDIX D
COMPREHENSION TEST

Room # ()

Comprehension Test

- 1) The researcher will draw how much blood?
a. Very small amount b. Medium amount c. Large amount

- 2) How many times will the researcher draw blood?
a. 1 time b. 2 times c. 3 times

- 3) The study will last how long?
a. 1 week b. 6 weeks c. 6 months d. 1 year

- 4) Who was this study made for?
a. Nurses b. Tennessee residents c. Nursing home residents

- 5) If you signed the consent form it would have been?
a. Voluntary b. Mandatory c. Recommended

VITA

Douglas H. Walters was born in Barbertown, Ohio on June 12, 1962. He attended elementary school in Hilham, Tennessee and graduated from Livingston Academy High School in June 1980. For the next five years he attended several universities and earned a Bachelor of Science degree in Biology from Middle Tennessee State University. In the fall of 1985 he began study toward a master's degree in nursing at the University of Tennessee. In December 1987 he completed the requirements for a Master of Science in Nursing.