THE ROLE OF FAMILY PARTICIPATION IN A MEDICATION INFORMATION PROGRAM ON SCHIZOPHRENIC CLIENTS' MEDICATION BEHAVIORS: A REPLICATION

by

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DEDICATION

This thesis is dedicated to my mother, Jean Heckbert, and to the memory of my father, Bill Heckbert, who taught me to turn lemons into lemonade. It is also dedicated to my children, Jake, Will, and Kate, who helped keep me grounded and in touch with what is real and important during this whole process.
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ABSTRACT

The purpose of this study was to determine if involving family members in a schizophrenic medication education group influenced the medication adherence of their schizophrenic family member.

Six schizophrenic clients and five family members participated in the study. All of the clients were male, four of the family members were female. Several ethnic groups were represented. Little change was noted in the schizophrenic clients' medication adherence behaviors on the two questionnaires utilized two months following family member attendance to the medication education group. However, family members perceptions of medication adherence more closely resembled those of their schizophrenic member two months following the group.
CHAPTER I

Introduction

Schizophrenia, one of the more serious of the major psychological disorders, affects more than one percent of the adult population under the age of fifty-five in this country (Aiken, 1987; Brooker, 1990; Rosenhan & Seligman, 1984). Some characteristics include: incoherence of speech and thought, prominent hallucinations, bizarre delusions, blunted or inappropriate affect, deterioration in social and occupational functioning, and a lack of self-care.

People with schizophrenia experience a high incidence of relapse and hospital recidivism as a result of the severity of the symptoms. Nonadherence to medication regimens and patient lack of understanding of the therapeutic benefits and side effects of these neuroleptic medications have contributed to the relapse rate (Anderson, Hogarty & Reiss, 1981; Ayd, 1976; Davis, 1975 Eckman, Liberman, Phipps, & Blair, 1990; Hogarty & Goldberg, 1973; Kane, 1983). The medication nonadherence rate for schizophrenics, among the highest of all
illnesses, is reported to be in the 40 to 50% range (Diamond, 1983; Kane, 1983). An estimated 40% of those started on neuroleptic medications discontinued their use within the first year following hospital discharge (Hogarty & Goldberg, 1973). Without appropriate neuroleptic chemotherapy, approximately 70% of the patients relapsed during the first year after discharge from the hospital (Hogarty, 1984).

Other factors that contributed to the relapse rate were poor social skills, unwillingness or inability to comply with treatment regimens, and a decreased ability to cope with environmental stresses (Falloon, 1984; Gallant, 1983). Interpersonal qualities related to social connectedness have been linked to the course and treatment outcomes of schizophrenic illness. Levels of expressed emotion, differing communication patterns, stressful life events, unfavorable family atmosphere, and other environmental stressors also were identified as contributors to symptom relapse (Brown, Birley & Wing, 1972; Goldstein, Rodnick, Evans, May & Steinberg, 1978; Leff, Kuipers, Berkowitz, Vaughn, & Sturgeon, 1983; Leff, Kuipers, Berkowitz, Fries & Sturgeon, 1984; Luckoff, Snyder, Ventura & Nechterlein, 1984; Singer & Wynne, 1966; Vaughn & Leff, 1976; Vaughn & Leff, 1981; Vaughn, Snyder, Freeman, Jones, Falloon & Liberman, 1982). Additionally, relapse in psychotic symptomatology has been shown to be
initiated by hostile, critical, or emotionally overinvolved attitudes directed towards the patients by their relatives (Brown et al, 1972; Kuipers, 1979; Vaughn & Leff, 1980).

Researchers and clinicians have identified the social variables of network size, density, relationship permanence, clustering (a group of individuals having a greater density of interconnection with each other than any of them has with others), stability, multiplexity (the extent to which network members have multiple role relationships with each other) and frequency of social or interpersonal contact as relevant factors influencing symptom relapse (Beels, 1981; Chrisman, 1977; Garrison, 1978; Lehman, 1980; Liberman, 1982; Lipton, Cohen, Fisher & Katz, 1981; Pattison, deFrancisco, Wood, Frazier & Crowder, 1975; Sokolovsky, Cohen, Berger & Geiger, 1978; Tolsdorf, 1976).

Alterations in social-environmental stressors have been cited as precursors to symptom relapse among medication compliant patients (Hirsch, 1983; Leff, Hirsch, Gaind, Rohde, & Stevens, 1973; McEvoy, Howe, & Hogarty, 1984). In contrast, prevention of relapse has been shown to occur when families can provide adequate problem-solving strategies and a positive-neutral family atmosphere (Hahlweg, Feinstein, Muller, & Dose, 1989). It would, therefore, seem imperative that the health care community
do its utmost to bolster the abilities of families to assist their ill members to deal with their disease, including adherence to medication regimens.

Statement of the Problem

Despite the known benefits of neuroleptic medications for schizophrenic patients, medication non-adherence and the resulting relapse has continued to be a major problem for this population. Reasons for medication nonadherence included dysphoric and extrapyramidal side effects, cognitive deterioration, drug regimen complexity, and the failure of health care providers to educate patients and their families about the benefits of prophylactic, long-term maintenance medication (Eckman et al., 1990). The value of educational programs specifically designed to improve medication adherence in the schizophrenic population has been poorly addressed, especially in the nursing literature. The use of family education and intervention programs to decrease the rate of relapse in schizophrenics has only recently been studied (Abramowitz & Coursey, 1989; Falloon, Boyd, McGill, Williamson, Razani, Moss, Gilderman, & Simpson, 1985; Hahlweg et al., 1989; Hogarty, Anderson, Reiss, Kornblith, Greenwald, Javna, & Madonia, 1986). These programs, emphasizing family communications, involvement in the client treatment plan,
and problem solving, have shown promise in decreasing client symptomatology and hospital recidivism.

However, there has been little evidence that these psychosocial interactions would be effective without maintenance chemotherapy. Appropriate pharmacotherapy remains the foundation for all treatment of schizophrenics (Hogarty et al., 1986). The emerging evidence that suitable family involvement improved outcomes for the schizophrenic client suggested that involving the family in medication education groups would improve medication adherence outcomes.

**Purpose**

The purpose of this study was to determine whether a medication information program presented to schizophrenic clients and at least one family member impacted the medication adherence behaviors of the schizophrenics. This study was a replication of an earlier study by Ingram (1987) who attempted to determine if including family members in medication education groups for schizophrenics improved the schizophrenics' compliance with their medications.

**Original Study.** Ingram, using a sample of five, investigated medication adherence following medication education. A didactic presentation on neuroleptic medications, presented by an experienced psychiatric
nurse, was evaluated in terms of its effect on medication adherence behaviors of schizophrenic clients whose family members attended the same educational program with medication adherence behaviors of schizophrenic clients whose family members did not attend the program.

The program content included: 1) theoretical perspectives on schizophrenia; 2) examples of the physiological impact of the more common neuroleptic medications on the brain; 3) the identification of routinely prescribed medications used in the treatment of schizophrenia and the usual dosage ranges; 4) descriptions of the more common side effects and effective methods of dealing with them; 5) an opportunity for clients and their families to discuss concerns and/or ask questions regarding program content. The clients were from a community oriented behavioral health out-patient clinic and were selected by clinic staff.

A convenience sample of three adult schizophrenics (differentiation within the diagnosis was not available) and two family members completed two assessment tools immediately following the medication education group (T1) and approximately two months later (T2): The Medication Adherence Assessment Tool (MAAT) developed by Ingram (1987) and the Self-Report Scale Predictive of Drug Compliance (SSPDC) developed by Hogan, Awad & Eastwood (1983). A comparison of responses on the MAAT indicated that both the
schizophrenics and their family members provided much more complete information on medications and medication taking behaviors at T2 than they did at T1. Responses did not change from T1 to T2 for the schizophrenic taking the class alone. The responses of this subject were very complete in both instances.

All schizophrenics and families showed improved total scale scores on the SSPDC from T1 to T2. However, there was a greater decrease in the mean scale scores for family members than for the schizophrenic clients.

To determine similarity of perception of medication adherence behaviors, a comparison of the total and mean scale scores for the SSPDC indicated that the two schizophrenics with family members achieved higher scores across both time periods in comparison to the score of the one client who attended the presentation alone. The level of adherence was perceived similarly by family members and clients and both perceived improvement in medication behaviors over time.

Results were inconclusive because of the small sample size. Ingram indicated however, there seemed to be a trend towards improved medication adherence behaviors on the part of the schizophrenic and perceptions of improved medication adherence behaviors from the viewpoint of the families in the Ingram study. It would, therefore, be important to those in the mental health community treating
schizophrenics to learn if these trends held up in a larger study.

**Significance**

One of the tasks of psychiatric nursing has been to co-ordinate between biomedical science and behavioral science in the "maintenance of mental health and the prevention/limitation of psychiatric dysfunction through the provision of care to individuals, families and communities" (McBride, 1990). According to Peplau (1989), mental health nurses could help clarify and solidify the domain of psychiatric nursing, by developing and utilizing opportunities to bring the "facts" of psychiatric disorders and their treatments into clinical practice. With the eventuality of Diagnosis Related Groupings (DRG's) coming to mental health care and the Joint Commission of Accreditation of Healthcare Organizations' (JCAHO) emphasis on outcomes of treatment, nurses must begin to delineate outcomes of specialized nursing interventions in relation to specific events (Pothier, Stuart, Puskar & Babich, 1990).

A psychoeducational group presented by the mental health nurse may provide schizophrenics and families a better understanding of the schizophrenics' needs in relation to their medication regimens. Family members may have inadequate or erroneous information regarding the
disease of schizophrenia and thus may negatively impact compliance patterns of the ill family member. High levels of expressed emotion (hostile, critical, or disappointing comments) and lack of positive reinforcement may also have deleterious effects on patient relapse and compliance with medical treatment (Leff, Kuipers, Berkowitz, Fries & Sturgeon, 1982; Hahlweg et al., 1989; Vaughn & Leff, 1976). The simultaneous presentation of didactic information to both the schizophrenic and family members might provide them with positive opportunities to become more active in problem solving, treatment planning and implementation and supportive strategies.

Health care providers must interrupt the medication nonadherence behaviors of schizophrenics if the foundation is to be laid for further psychosocial interventions and hospital recidivism is to be decreased (Anthony & Nemec, 1984). If appropriate family involvement can interrupt nonadherent behavior, the development and addition of family intervention programs to treatment programs for schizophrenics is critical.

**Summary**

The purpose of this study was to determine whether a medication education program presented to schizophrenics and at least one person, who the client identified as a family member, impacted the medication adherence behaviors
of the schizophrenic. Maintenance chemotherapy has been the major deterrent to symptom relapse in the schizophrenic. Yet, despite the known benefits of neuroleptic medications, medication non-adherence has continued to be a major problem for this population. Emerging evidence that appropriate family involvement improved outcomes for the schizophrenic client suggested that involving the family in medication education training would improve medication outcomes.
CHAPTER II

Theoretical Framework and Review of the Literature

This chapter will describe the theoretical framework and review the literature.

Theoretical Framework

Reciprocal determinism (Bandura, 1974; 1977; 1983) was used as the theoretical basis for this study. The three major elements of this social learning model were environmental influences, cognitions, and behavior. Each element or component interacted with the others through a "bidirectional influence." See Figure 1.

The influence of social or environmental factors has been cited in the literature as relevant to health behavior outcomes for schizophrenics as well as other clients (Caplan, 1974; Falloon et al., 1985; Hahlweg et al., 1989; Hogarty et al., 1986). The social psychiatrist, Caplan (1974), stated that:

Significant others help the individual to mobilize his psychological resources and master his emotional burden, they share his tasks; and they supply him with extra supplies of money, material, tools, skills and cognitive guidance to improve his handling of the situation (p. 6).
Figure 1. Schematic representation of the bidirectional reciprocal influence of model concepts. Adapted from Ingram (1987), p. 6.
The mental health nurse, because of the amount of client contact time, has had a tremendous opportunity to influence the environmental impact on the health behavior of the clients. The regular questioning by nurses of their clients' self-medication regimens and side effects experienced has been shown to help promote medication compliance (Van Putten, 1982).

In this interpretation of the reciprocal determinism model, families as well as the mental health professionals were considered to be part of the environmental component: factors external to the individual. Families have often been the clients' principal and most continuous source of physical and emotional support, yet they were frequently not considered a resource or included in client treatment programs (Falloon, Boyd, McGill, Razani & Strang, 1981). A number of studies seemed to confirm that family members could have a positive influence on the medication compliance of their schizophrenic member (Falloon et al., 1985; Hahlweg et al., 1989; Parkes, Brown, & Monk, 1962; Wilcox, Gillan & Hare, 1965).

The second element of this reciprocal interaction model was the cognitive or knowledge level of each person. Bandura stated the "information processing capacities" provided the foundation for responsibly informed behavior (1974, p. 860). Cognitive capacities, in part, determined which external phenomena were recognized, whether they were
deemed important by the individual, and whether these perceptions would have any lasting effects. The way information was transmitted defined how it would be organized in the future. Without relevant information and the cognitive capacity to process it, individuals would be denied the ability to effectively cope with the stresses of daily life. Bandura assumed that individuals had the capacity to learn from observation and meaningful instruction, and that this directly influenced behavior.

The final element of Bandura's model (1983) was behavior. Bandura saw behavior as a psychosocial occurrence. Prior to the development of his theoretical perspective, determinates of behavior were considered to be unidirectional with either environmental or internal factors influencing the behavior. Bandura proposed that psychological functioning was a perpetual reciprocal interaction among environmental, cognitive, and behavioral phenomena, and developed reciprocal determinism as the model for describing psychosocial phenomena at the level of intrapersonal development, interpersonal transactions, and interactive functioning.

Reciprocal determinism (Bandura, 1974) was used in this study as a model for understanding the medication-taking behavior of schizophrenic clients (See Figure 1). This model assumed the interdependence between the three major elements and provided the nurse the opportunity to
individualize treatment plans utilizing each of these components. The three model components were specifically outlined for this study as: 1) **environmental condition**: the mental health care nurse, as an authoritative and influential health care provider, provided an educational program which included family members as well as schizophrenic clients; 2) **cognitive condition**: individual knowledge gained by family members and schizophrenics as a result of a relevant medication education program; 3) **behavioral condition**: medication adherence practices of each schizophrenic client as well as the schizophrenic and family member self-reports regarding medication-taking behaviors.

This study included the three major components and focused on one feature of the reciprocal link between environment (family) and the individual behavior of the schizophrenic client.

**Review of the Literature**

**Environmental Condition**

This study considered two components of the environmental condition of the schizophrenic: the therapeutic environment and the familial environment.

**Therapeutic Environment.** The therapeutic environment of the schizophrenic had undergone a dramatic change over the last three decades resulting from a change in the focus
of treatment of the severely mentally ill (SMI). Until the late sixties, SMI patients were maintained in large institutional settings, frequently far from their families and home communities (Bachrach, 1976). This isolation seemed to dilute patients' motivation to return home and produced symptomatology far beyond that of their diagnosed conditions (Mechanic, 1969; Stanton & Schwartz, 1954). As the advent of psychotropic medications made it feasible to maintain many patients in less restrictive settings, mental health professionals became increasingly concerned about the long-term effects of hospitalization on the patients that they were observing (Cutler, 1985).

In response to these observations, legislators mandated decreases in the numbers of institutionalized patients and the establishment of community mental health programs to care for SMI's in the least restrictive environments possible (Kerfoot & Crowell, 1984). The Mental Health Law of 1973 defined "least restrictive" environment as:

...a person should not be hospitalized with drastic curtailment of liberty involved, if he can be treated in a setting less restrictive than an institution as required by the constitutional principle of the least drastic means. The Constitution requires that whenever a government is going to restrict a person's liberty against his will in order to accomplish a legitimate governmental objective, it must impose the least drastic restriction necessary (Scheerenberger, 1976, p. 126).
Even though legislatures mandated treatment for the mentally ill in the least restrictive environment, it was documented that less than 50% of those discharged from inpatient facilities ever received outpatient treatment (U.S. Steering Committee, 1981). Opponents of deinstitutionalization stated that the transition of patients from hospitals to the community was frequently neither useful nor humane, as confirmed by the development of community "backwards" (Bassuk & Gerson, 1978; Lamb & Goertzel, 1972) and the "revolving door syndrome" (Redlich & Kellert, 1973; Talbott, 1979). However, Wyatt (1980) felt that the majority of schizophrenic clients quickly returned to functioning within their community following treatment for a psychotic relapse. In spite of these discrepancies in findings, the reoccurring patterns of relapses and rehospitalization continued to make schizophrenia one the nation's primary mental health problems (Aiken, 1987; Brooker, 1990, Rosenhan & Seligman, 1984; Wyatt, 1980).

It has been said that the problem was not one of deinstitutionalization but "transinstitutionalization" (Talbott, 1979). Cutler (1985) stated that SMI's might currently be found in a variety of living situations, including group and foster homes, jails, high security hospitals and court ordered after care treatment facilities. Talbott (1979) described that the abundance of
support and living situations helped create the modern human systems' problem of patients "falling through the cracks." This problem led Erickson & Hyerstay to state, "The ideals of community treatment have become a matter of empty words rather than practice" (1980, p. 35). In summary, community aftercare treatment was all too frequently fragmented, inconsistent, or totally lacking.

The deemphasis on institutionalization of schizophrenic clients as a prominent part of their treatment regimes provided the nurse with a pertinent role in the outpatient and community therapeutic environment of the schizophrenic (Krauss, 1991). Because nurses spend a great deal of time relating to persons with health needs, they become an influential part of clients' therapeutic environments with a potential for greatly impacting health behaviors. Nurses had traditionally educated clients both in the characteristics of diseases, using a "target symptom" approach to identify relapse phases, and in the details and rationales of treatment (Hogue, 1979). By integrating biomedical knowledge and behavioral science for schizophrenic clients and their families, nurses could make inroads in limiting psychiatric dysfunction (McBride, 1990).

Familial Environment. A review of the literature relative to social interactions and schizophrenic clients indicated that these people had smaller social networks
than those without psychiatric disorders (Pattison et al., 1975; Sokolovsky et al., 1978). Evidence suggested that schizophrenics were more adept at organizing opportunities for solitude than for social interaction (Harris, 1990); therefore, the extent of possible social resources seemed drastically curtailed. Tolsdorf (1976) found that the networks of schizophrenic clients contained a higher proportion of family members than the networks of other medical clients.

This tendency toward high familial network membership was problematic according to Brown et al. (1972) because of the quality of the interactive relationships within schizophrenic families. It has been estimated that 50% to 70% of schizophrenic clients discharged from the hospital return home to family members (Brooker, 1990; Lamb & Oliphant, 1978; Minkoff, 1979; Smith & Birchwood, 1987). Evidence has amassed that claim interpersonal processes within the familial environment as one of the most valid predictors of relapse among schizophrenics (Leff, 1975). According to Tarrier, Vaughn, Lader, & Leff (1979) the quality of the emotional relationship between schizophrenic clients and their families often contributed most to precipitating relapses, despite the fact that preventive antipsychotic medication could improve these clients' abilities to cope with the strain of everyday living.
It has been found that schizophrenic families frequently had a high index of hostility, interpersonal or social criticism, or emotional overinvolvement causing the schizophrenic client to be more susceptible to relapse (Vaughn & Leff, 1976; Berkowitz, Kuipers, Eberlein-Frees, & Leff 1981). In families where the level of high expressed emotion was diminished, the clients' ability to cope was improved (Berkowitz et al., 1981; Leff et al., 1982).

In contrast to the detrimental effects families might have on schizophrenics, there was also research indicating that appropriate family involvement could prove to be vital in the improvement of outcomes for schizophrenic clients. Longitudinal studies with medication-compliant schizophrenics comparing in-home family therapy (focusing on enhancing the stress-reducing capacity of the clients through improved understanding and skills in problem-solving) with clinic-based individual supportive care indicate that the family therapy intervention was superior in preventing major symptom relapse (Falloon, Boyd, McGill, Razani, Moss & Gilder, 1982; Falloon et al., 1985; Falloon, McGill, Boyd, & Pederson, 1987). Snyder & Liberman (1981) also advised that there was a positive correlation to relapse reduction when family members were educated about schizophrenia. In a one-year follow-up study, Hogarty and Anderson (1986) found a significant main effect for family psychoeducation in forestalling relapse.
Leff et al. (1984), in a two year follow up study, found that a significant reduction in relapse rate was achieved in schizophrenics living in families with high expressed emotion when family members were involved in the combination of an educational program, relative's group, and family therapy. It was unknown at the conclusion of the study which of these interventions contributed the most to the reduction in relapse, or whether all three interventions were necessary.

Reported intervention-educational programs for families of schizophrenics varied greatly in their content, making it difficult to determine which aspects of these programs were significantly related to relapse prevention; i.e. goals of the sessions, didactic material presented, program length, number and location of sessions, whether clients attended sessions, number of family members attending sessions (Goldstein, 1984). What is now needed is definition of was which specific components will result in optimal recovery.

In summary, both the therapeutic and familial environments contribute to increased medication adherence and to the successful maintenance of the schizophrenic client outside of the hospital environment.

Cognitive Condition

Clinicians and researchers have suggested that specific kinds of education and information about
medications, their purposes, and side effects might promote client adherence to treatment regimes. However, studies conducted with medical clients have indicated that client retention of information was a problem. Ley (1973) found that after five minutes clients forgot approximately half of the doctor's instructions and remembered best that portion of the instructions that were given in the first third of the presentation. Other studies indicated that client non-adherence to medication regimens was associated with a lack of adequate information about the purposes of the medications and how they should be taken (Caplan, Robinson, French, Caldwell & Shinn, 1976; Hulka, Cassel, Kuipers & Burdette, 1976; Joyce, Caple, Mason, Reynolds & Matthews, 1969; Svarstad, 1976).

Dunbar & Stunkard (1979) showed that knowledge of and the complexity of the regimen were important factors influencing client adherence. According to Blackwell (1979) approximately two thirds of the problems with medication adherence were related to a lack of understanding on the part of the client. Knowledge of medication identification, frequency and purpose has proved to be central to improved client adherence (Diamond, 1983; Hogan et al., 1983). Schizophrenic clients tended to perceive their medications in relation to their side effects rather than their therapeutic effects (Cohen & Amdur, 1981) and without an understanding of the
biochemical and physiological reasons for the medications, saw them merely as tranquilizers (Kerfoot & Crowell, 1984).

However, Becker & Maiman (1980) stated that information about the relevancy between knowledge and adherence behavior was neither consistent nor obvious. Some studies found no distinct relationship between the amount and type of client information and adherence to medication therapy (Haynes, 1976; Podell, 1975; Sackett, 1976). Becker & Maiman (1980) stated that it was important to recognize, that under certain circumstances, some kinds of information might not be adequate to assure patient cooperation. He advised that differing teaching methods might enhance and provide improved communication of information to the client; i.e. specific, individualized, easy to understand instruction, brief, careful organization of material necessary for adherence, repetition of pertinent material, and both oral and written instructions so the client would have something to refer to after the teaching session.

Unpleasant side effects was one of the primary reasons schizophrenics gave for discontinuing medication therapy (Cohen & Amdur, 1981). According to Beck & Rush (1975), the "cognitive interpretation" of an event determined if the client saw the impact of the event of the stressor to be positive or negative. They advocated that if schizophrenic clients could learn to categorize side
effects into specific groups, i.e. "severe vs. non-severe" or "tolerable" or "negligible," they would suffer less than if they merely considered the development of side effects from medication to be "severe."

Linden & Chaskel (1981) also found educating the client in improved methods of coping with medication side effects to be beneficial. Furthermore, a number of studies indicated that education about schizophrenia and the part stress and its management played was helpful for the families as well as the schizophrenic clients (Falloon & Pederson, 1985; Hogarty, 1984; Kane, DiMartino & Jimenez, 1990; Noh & Turner, 1987).

Hogarty and Anderson (1984) found that not only did family psychoeducation reduce the relapse rate for schizophrenics from 41% to 19%, and social skills training reduced the rate from 41% to 20%, but that combining the two treatment effects brought the relapse rate to 0% during the first year post discharge period. This would indicate that the best effects could be obtained by educating and treating the family as well as the schizophrenic client.

There was little in the literature regarding education programs implemented by nurses designed to improve medication regime adherence by the schizophrenic client (Cohen & Amdur, 1981; Common, 1979; Kane et al., 1990; Moller & Wer, 1989; O'Brien, 1978; Schlofane, 1977). Moller & Wer (1989) commented that very few programs
involved the simultaneous teaching of the schizophrenic client and family members. Slavinsky & Krauss (1983) believed this lack of emphasis was due to the difficulty in exploring sensitive, personal treatment outcomes in the schizophrenic population. More research was needed to determine which treatment modalities were most efficient, effective, and cost-productive in maintaining the schizophrenic client at a functional level in the community. The mental health community fell short of the development of a comprehensive effective approach to the treatment of schizophrenia (Keith & Matthews, 1982), of which the issue of medication adherence was a significant component.

In summary, the knowledge and complexity of the regimen are important factors in influencing adherence to medication regimens. Additionally, families' knowledge seems to impact the medication adherence behaviors of the schizophrenic client.

Behavioral Component

Client non-adherence to medication regimens is epidemic in medical treatment. The question could be posited as to whether it was even more extensive in the mental health field where the nature of the clients' illnesses could strongly impact their judgment, insight, and stability.
Treatment regimen adherence was a critical behavior in the schizophrenic, necessary to reduce symptom relapse. For our purposes, adherence was defined as the extent to which a person's behavior was in agreement with medical counsel (Babiker, 1986).

The advent of antipsychotic medications altered the entire treatment program for the schizophrenic client. Most people diagnosed as schizophrenics had symptoms that favorably react to antipsychotic medications. With maintenance medications many of them were able to maintain themselves out of the hospital and function adequately in the community, while discontinuance of the medications increased the risk of relapse, thus impairing the schizophrenic's insight and judgement making the client less likely to accept treatment (Babiker, 1986).

The importance of continuing these medications to prevent relapse and facilitate community adjustment and integration has been confirmed (Davis & Gierl, 1984; Falloon, 1984). Research indicated that approximately 70% of those schizophrenics studied showed a substantial improvement on antipsychotic medications while almost none showed a worsening of symptomatology (Cole, Goldberg & Davis, 1966). In contrast, the administration of a placebo resulted in only 25% improving and 45% worsening.

Hogarty (1984), in a similar study comparing symptom relapse rates of clients stabilized on psychotropic
medications and clients given placebo therapy, found that the medication group suffered a 15% rate of symptom relapse, while the placebo group had a relapse rate of 65%. Some researchers suggested that psychotropic medications insulate schizophrenics from a continuum of stressful social stimuli, thereby aiding their adjustment to society (Schooler & Levine, 1983).

Gaining client cooperation was a crucial component of all recommended and prescribed regimens requiring medication self-administration (Becker & Maiman, 1980). Researchers have contended that developing a therapeutic environment that would increase the likelihood of the clients' informed use of medication is the most critical task in health care today (Dunbar & Stunkard, 1979; Frances & Weiden, 1987). It has been estimated that approximately one-half of all clients failed to receive the full benefit of their medication therapies because of inadequate adherence to the prescribed regimen (Haynes, 1976).

As important as it would seem for schizophrenics to adhere to their medication regimens, many do not. It has been reported that between 25% and 50% of schizophrenics did not take their medication as prescribed after discharge (in Sullinger, 1988). Some reasons for this have already been discussed, i.e. complexity of the medication regime, uncomfortable, unexplained and unexpected side effects, lack of understanding of the purposes of the medication and
ineffective coping methods of dealing with stress). Since many schizophrenics were advised to take maintenance doses of medications which do produce uncomfortable side effects, it could be predicted that these clients would be at high risk for medication nonadherence. In addition, the initial discontinuation of the medication might not make the client feel worse (Blackwell, 1976).

Clients' understanding and interpretation of their altered physiology brought on by their medicated state might influence medication adherence (Hogan, Awad, & Eastwood, 1983; Van Putton, May, Marder & Wiltmann, 1981). It might additionally be presumed that the symptomatic impaired judgement of schizophrenics contributed to their poor medication adherence (Sullinger, 1988). Relevance of family factors has also been indicated as an issue important to medication adherence (Frances & Weiden, 1987). And it has been noted that some schizophrenic clients seemed to actively seek a delusional state by discontinuing their medication, preferring the delusions to decreased symptomatology (Van Putton, Crumpton & Yale, 1976). These authors also determined that clients who adhered to medication regimens and those who did not differed in their attitudes toward treatment regime adherence and clinical symptomatology.

To further confuse the issue of understanding mediation nonadherence behavior among schizophrenics,
Blackwell (1976) contended that the poor adherence argument tended to disappear under scrutiny. He stated that clients who were most likely to participate in a study were not necessarily indicative of the whole population; they might comply more willingly to their treatment regime. He also stated that measurement problems might skew research outcomes for adherence/nonadherence rates. He contended that most studies focused on schizophrenics omitting medications and failed to include incidents of over medication, medication irregularity, and under medication. If these suppositions are accurate, the matter of medication nonadherence might be of an even greater magnitude.

In contrast to the research findings indicating a positive correlation between improved medication adherence behavior and improved knowledge about medications and schizophrenia, Soskis (1978) proposed that the schizophrenic client appeared to have a considerably higher level of knowledge than medical inpatients about the medication they were taking. Notwithstanding this increased knowledge, only 56% of the schizophrenic clients stated they would willingly adhere to their treatment regime. Alternatively, 93% of the medical clients were willing to adhere to their regime. It became obvious that data surrounding the relationship, knowledge, and
acquisition of medication adherence behavior was inconsistent. More conclusive data was needed.

**Summary**

The above discussion highlights the magnitude and complexity of the problem of medication nonadherence with schizophrenics. Using Bandura's (1974) theory of reciprocal determinism, it could be suggested that many interactive environmental, cognitive, and behavioral factors influenced clients' abilities to adhere to treatment regimens. Research indicated that explicit, multifaceted psychoeducation of both clients and their families might favorably impact the relapse rate for schizophrenics. The nurse could be in a unique position to facilitate this education.
CHAPTER III

Methodology

This chapter will discuss design, research questions, sample selection, definitions, human subject review, clinic setting, data collection procedure, instruments and data analysis.

Research Design

This quasi-experimental study utilized a pretest-post-test comparison group design and was a replication of an earlier study by Ingram (1987). Three instruments: the Demographic Survey, the Medication Adherence Assessment Tool (MAAT), and the Self-Report Scale Predicative of Drug Compliance (SSPDC) (Appendix A), were given to all participants immediately preceding and approximately two months following an hour long medication education class. A convenience sample of five subjects in the family group and one subject in the comparison group was obtained. Subjects were placed into the comparison group and family group on an as available basis.
Sample Selection

Subjects for this study were recruited from the day treatment program of the selected institution. The members of this program were selected because of the high percentage of schizophrenic clients participating and because of the already established medication education program conducted with this group of clients. In addition, this was the same facility in which the original study was conducted, therefore increasing the possibility that the study participants would be demographically similar to the participants of that study.

The facility serviced an ethnically diverse population, which corresponded with the diversity of the Southwestern community in which it was located. All members of the day treatment program were allowed to attend the sessions; however, only those meeting the established criteria for the study and their family members were included in the data base.

Criteria for inclusion in the study included: 1) a Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised (DSM III-R) diagnosis of schizophrenia, 2) the ability to read, write and understand English as determined by clinic personnel, 3) orientation to person, place and time, and 4) family members available in the community who were also willing to participate in the study.
Following the identification of prospective subjects by clinic personnel, a brief description of the study and a request for client and family participation was made to the clients by clinic personnel. Additionally, personnel contacted prospective subjects by phone encouraging them and their family members to attend and participate in the study.

Research Questions

1. Were there characteristic differences between the clients with family members and clients without family members attending the medication education group?

2. Were there differences between the medication compliance behaviors of schizophrenics whose family members attended the medication education program and of those whose family members did not attend the program?

3. Were there differences between the schizophrenic client's and at least one family member's perception of the medication compliance behaviors following program attendance?

Definitions

Schizophrenic Client. Any adult diagnosed with continuous characteristic schizophrenic features for a minimum of six months and delineated by the following criteria: 1) existence of specific psychotic symptoms
during the active stage of the illness; 2) characteristic symptoms involving multiple psychological processes, including disturbances in thought processes; 3) deterioration from previous levels of functioning; 4) onset before age 45 (unless specified as late onset); and 5) the disturbance was not due to an Affective Disorder or Organic Mental Disorder (APA, 1987). Note: This definition has been modified from the original study to incorporate DSM III-R diagnostic criteria.

Adherence. A constant external criterion which exists for both the receiver and prescriber of medication that is understood by and acceptable to both parties (Barofsky, Sugarbaker & Mills, 1979). For the purposes of this study, adherence was defined as the "medication taking behavior(s) of chronically ill schizophrenic clients which promote or maintain a recognized functional level and was measured by questions in the Medication Adherence Assessment Tool (MAAT) and Self-Report Scale Predictive of Drug Compliance (SSPDC) questionnaires (Ingram, 1987, P.23) (See Appendix A).

Family. "A group of individuals usually composed of two generations and two sexes where each individual: 1) expresses different needs, prerogatives and obligations; 2) establishes relationship by firm erotic and affectual ties; and 3) forms a shelter for other group members against the larger society" (Hofling & Lewis, p. 51). For the purposes
of this study, whoever the schizophrenic client identified as a family member was defined as family.

**Human Subjects Review**

Following human subjects' approval by the Ethical Review Committee of the University of Arizona College of Nursing (See Appendix B), the proposal was submitted to a local community mental health agency for review and approval by the research protocol committee. Participants were asked to sign a consent form (See Appendix C) indicating their willingness to participate in the study, their understanding of the confidentiality of their participation in the study, and their ability to withdraw from the study without repercussions if they so chose.

**Clinic Setting**

The selected agency was located in a metropolitan Southwest city and was that state's largest non-profit community mental health center. It had treatment programs for children, adolescents and adults, for chemical dependency and for the seriously mentally ill. (LaFrontera Center, Inc., 1991). The total number of clients seen within the selected agency for the fiscal year 1991 was 6066. Of those client visits, approximately 50% of the services were for the 989 chronically mentally ill clients (C. Howell, personal communication, October 9, 1991).
Medication Information Program

A previously established clinic-conducted medication information program was selected because of the similarity between its established content and the medication adherence focus of the study. The program content included: 1) theoretical perspectives on schizophrenia; 2) discussion of the physiological effects to the brain of routinely prescribed neuroleptic medications; 3) presentation of the commonly prescribed medications used in schizophrenia treatment and their frequently prescribed dosage ranges; 4) descriptions of the most commonly experience medication side effects and effective methods for dealing with these unpleasant experiences; and 5) a period for questions about the program content and discussing client concerns.

To this established program was added the opportunity for families to attend and learn with their schizophrenic member. The program was to be approximately 45 minutes long and scheduled at a time convenient for clients and family members to attend. The program instructor was an experienced psychiatric nurse directly involved with the day treatment program at the mental health center.

Data Collection Procedure

Prior to the medication education presentation, all clients and family members completed the Demographic
Survey, the Medication Adherence Assessment Tool (MAAT), and the Self-Report Scale Predictive of Drug Compliance (SSPDC), or the family member parallel forms (See Appendix A). Clients and family members were encouraged to complete all instruments to the best of their abilities. The investigator provided necessary instruction clarification and word definitions.

Approximately two months following the medication education presentation, the MAAT and the SSPDC questionnaires and a self addressed stamped envelope were sent to participants homes. The participants completed and returned the questionnaires by the self-addressed envelopes. For participants who did not respond to the initial mailing, one follow-up telephone call and one home visit was conducted to obtain completed questionnaires. Clinic personnel also set aside time for clients to take the post-test during regular clinic visits. The two month lapsed time between the test and retest collections allowed time for behavior changes to occur.

**Instruments**

This study used three questionnaires: the demographic survey, the Medication Adherence Assessment Tool or MAAT, and the Self-Report Scale Predictive of Drug Compliance or SSPDC (See Appendix A).
Demographic Survey. The Demographic Survey was a 15-item multiple choice instrument asking the clients and family members information about age, race, education, living arrangements, marital status, employment, hospitalization, source of income and diagnosis. The format and instructions were clear and easily responded to.

Medication Adherence Assessment Tool (MAAT). The MAAT was developed by Ingram (1987) for the original study. It was a six-item scale made up of open-ended, semi-structured questions regarding medication adherence behaviors. It was designed for the purpose of assessing patient and family members' knowledge about specific medication adherence behaviors of the schizophrenic client. Since the format of the MAAT was open-ended rather than forced choice, the responses from the study participants were individualized. This format provided a valuable contrast and comparison to the two other instruments utilized in the study, which were of a forced choice format. Because of the previous limited use of the MAAT, no reliability and validity measures were available.

Self-Report Scale Predictive of Drug Compliance (SSPDC). The SSPDC, developed by Hogan, Awad, & Eastwood (1983), was a 30-item instrument obtained from a stepwise discriminant analysis of responses from 150 schizophrenic clients. An item by item preliminary validation, done in the form of discriminant classification, accurately
assigned 89% of the original sample to either compliant or non-compliant groupings. A second discriminant function analysis, entering the original 30 items in a stepwise fashion into the analysis until an optimal set of items for group membership was obtained, indicated the means for compliant and non-compliant patients to be 0.17 and -1.84 respectively with little overlap.

A preliminary cross validation was attempted on a reduced 10-item scale with a sample of 19 patients using therapist ratings of compliance levels as criterion resulting in a value of 68% agreement. Reliability analysis done on the original 30-item scale indicated an internal consistency of .93 (p<.001) and a test-retest reliability of .82.

Twelve items selected from the larger 30-item scale were used for this study. The selected items denoted the six discriminating highest mean scores for compliant and non-compliant responses. The scale was reduced so that clients and family members could complete the combined questionnaires in a reasonable amount of time.

The 12-item scale used for this study had practical limitations since no validity and reliability measures were available secondary to the small sample size of the original study. It is possible that the reduced number of items might have affected the psychometric properties of the instruments. However, the chosen items retained a high
degree of face validity and the range of variance of discriminant values between compliant and noncompliant responses reported for the original 30-item scale indicated that psychometric instrument properties might have been retained.

Responses for the modified 12-item instrument used in this study were formulated in a Likert format with response scores ranging from (1) "not at all" or 0% to (7) "always" or (100%). The highest level of medication adherence was being assigned the numerical value of (7). The lowest level of adherence was assigned the numerical value of (1). Several items, 7-12 (see Appendix A), required reverse scoring from the respondents in an effort to indicate greater knowledge of medication practices encompassing the schizophrenic illness. Individual item scores were added together to obtain a total estimate of each client's medication adherence level. Additionally, an adherence percentage score was determined using value comparisons between individual client's obtained scores and the total possible scale scores.

Data Analysis

It was anticipated that a variety of statistical analyses would be used to explain the findings. However, because of the small sample size, analysis was limited to frequency distribution data and visual comparisons of data.
Descriptive statistics were used to describe the data collected. A visual comparison of this data was done to determine homogeneity of the sample (Research Question One).

A comparison of low and high total scale scores and total scale score means were computed for time one (T1) and time two (T2) to indicate differences between the comparison group and the client with family group for the second research question: "Were there differences between the medication compliance behaviors of schizophrenics whose family members attended the medication education program and of those whose family members did not attend?"

A comparison of low and high total scale scores and total scale score means for T1 and T2 was also used to describe the difference between the schizophrenic client's and the family member's perception of medication compliance in the third research question: "Were there differences between the schizophrenic client's and at least one family member's perception of the medication compliance behaviors following program attendance?".

Summary

A medication education program was evaluated for the effects it had on influencing medication adherence behaviors on those schizophrenic clients whose family members attended the presentation and on those clients
whose family members did not attend the presentation. The subjects were clients at a Southwest community mental health center and participants in its day treatment program and their family members. Instruments used in data collection were a demographic survey, the MAAT, and the SSPDC. These instruments were administered to clients and their families prior to the medication education program and approximately two months after the program was completed. Comparisons of the data were made using descriptive statistics and frequency distributions.
Chapter IV

Results

This chapter will describe the sample and data specific to each research question.

Characteristics of the Sample

A convenience sample of ten adult chronic schizophrenic clients (seven with family members and three without family members) and seven family members were recruited from a local mental health clinic. From this original sample, six clients and five family members were included in the final data analysis. Two client/family member pairs had to be dropped from the study: one because the client was on no medication and the other because the family member could not be reached to complete the post-test. Two clients without family members were dropped from the study because they did not carry a diagnosis of schizophrenia or schizoaffective disorder (although clinic personnel believed one might in fact be schizophrenic or schizoaffective).
Results Related to the Research Questions

Research Question 1. Were there characteristic differences between the clients with family members and clients without family members attending the medication education group?

Client Characteristics with Family Members. Of the five clients with family members completing the study, all were male and between the ages of 19 and 32 (M=25.33). One was Hispanic, two were American Indian, and two were Caucasian (See Table 1).

Three clients were single, one was married, and one classified himself as other (See Table 2). Two clients had no children, one had one child, one had four children. One client did not answer the question regarding children. Three clients had an educational level of eighth grade or less, two had eleventh grade or less (See Table 3). One client was employed, four were on Supplemental Security Income (SSI) or Social Security Disability (SSD).

Three clients lived with their parents, one lived with his spouse, and one lived with a friend (See Table 4). Four clients lived with a family member, one lived within 20 miles of his family.

One client stated his diagnosis was catatonic schizophrenia, two were disorganized schizophrenics, and two were paranoid schizophrenics (See Table 5).
Table 1.

Clients and Family Members by Age, Sex, and Ethnicity

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clients with Family Members Attending the Program (n=5)</th>
<th>Family Members Attending the Program (n=5)</th>
<th>Clients with no Family (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEX</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>AGE</td>
<td>19 - 32</td>
<td>36 - 63</td>
<td>28</td>
</tr>
<tr>
<td>Mean</td>
<td>25.33</td>
<td>52.00</td>
<td></td>
</tr>
<tr>
<td>ETHNICITY</td>
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<td></td>
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</tr>
<tr>
<td>Hispanic</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td>American Indian</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
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<td>2</td>
<td></td>
</tr>
<tr>
<td>Black</td>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Variable</td>
<td>Clients with Family Members (n=5)</td>
<td>Family Members Attending the Program (n=5)</td>
<td>Clients with no Family (n=1)</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------</td>
<td>-------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Single</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Married</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Other</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>NO. OF CHILDREN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td></td>
<td>1</td>
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<tr>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td>1</td>
</tr>
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</table>
Table 3

Clients and Family Members by Education and Income

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clients with Family Members (n=5)</th>
<th>Family Members Attending the Program (n=5)</th>
<th>Clients with no Family (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EDUCATION</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>8th grade or less</td>
<td>3</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>11th grade or less</td>
<td>2</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>some college or trade school</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INCOME SOURCE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSI or SSD</td>
<td>4</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>No Income</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4
Clients' and Family Members' Residential and Proximity to Family Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clients with Family Members Attending the Program (n=5)</th>
<th>Family Members Attending the Program (n=5)</th>
<th>Clients with no Family (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RESIDE WITH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parents</td>
<td>3</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Spouse</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Relative</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Friend</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>PROXIMITY TO FAMILY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Live with</td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Live 1-20 miles</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Table 5.

**Clients and Family Members by Diagnosis**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Clients with Family Members Attending the Program (n=5)</th>
<th>Family Members Attending the Program (n=5)</th>
<th>Clients With No Family (n=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIAGNOSIS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catatonic</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disorganized</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Paranoid</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Undifferentiated</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Schizoaffective</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Don't Know</td>
<td></td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Family Member Characteristics. Five family members attended the program. Of these, one was male and four were female. They were between the ages of 36 and 63 (M=52). One was Hispanic, two were Caucasian, one was Black, and one was listed as other (See Table 1).

Two family members listed themselves as single, three were married. Two family members had two children, one had three children, one had four children, and one had six children (See Table 2). Two had an educational level of eighth grade or less, three stated they had some college or trade school education. Three family members said their source of income was SSI or SSD, two family members stated they had no source of income (See Table 3).

One family member lived with parents, two with their spouses, one with a relative, and one lived alone. Four stated they lived with family, one lived within twenty miles of family (See Table 4).

Family members were asked for their family member client's diagnosis. One family member reported that the client's diagnosis was disorganized schizophrenia, one was paranoid schizophrenia, one was undifferentiated schizophrenia, one was schizoaffective disorder (that client reported his diagnosis was paranoid schizophrenia), and one family member didn't know the diagnosis (See Table 5). It is interesting to note that clients and family members were not in agreement as to diagnosis.
Client Without Family. The client with no family members present was a 28 year old Hispanic male (See Table 1). He was single, had no children (See Table 2), had an educational level between eighth and eleventh grade and collected SSI or SSD (See Table 3). He lived alone, but within 20 miles of his family (See Table 4). He did not know his diagnosis (See Table 5). Upon visual comparison, he was similar to the clients with family members.

Research Question 2. Were there differences between the medication compliance behaviors of schizophrenics whose family members attended the medication education program and of those whose family members did not attend the program?

Medication Adherence Assessment Tool. On comparison of the responses to the Medication Adherence Assessment Tool (MAAT), little change in the completeness of answers from prior to the education group (Time 1; T1) to two months following the education group (Time 2; T2) was noted. The lack of adequate sample size (clients with family members: n=5; clients without family members: n=1) made drawing conclusions difficult. The pattern of little change, however, seemed to be consistent for both clients with family members and the client without a family member. In two cases, non-prescription drugs were listed at T2, where that space had been left blank at T1, however
there was also an instance where only psychotropic drugs were listed at T2, when the client had listed cardiac medications at T1. In no instances were dosages listed.

**Self-Report Scale Predictive of Drug Compliance.** A comparison of total scale scores was done on the Self-Report Scale Predictive of Drug Compliance (SSPDC) from T1 to T2 for clients with family members and the client without a family member. Only comparisons of frequency distribution data was done as the small sample size discouraged further statistical calculations (See Table 6).

The lowest total scores for clients with family members attending decreased from T1 to T2 on the SSPDC, however the highest total scale score from T1 to T2 increased slightly. There was a slight decrease in the mean total scale score achieved from T1 to T2. For the client who did not have family members attending, there was a slight increase in the total scale score.

In summary, a visual comparison of data for the MAAT indicated little change from T1 to T2. A lack of adequate sample precluded the computation of statistical procedures which would specifically speak to change differences on the SSPDC. A visual comparison of frequency scores indicated a slight decrease in mean scale scores at T1 for clients with family members attending and a slight increase at T2 for the client without a family member.
Table 6.

**Range and Total Scale Score Comparisons Across Two Time Periods for the Self-Report Scale Predictive of Drug Compliance**

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Immediately After Medication Group</td>
<td>Two Months After Medication Group</td>
</tr>
<tr>
<td>Family Members</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attended (n=5)</td>
<td>64.000</td>
<td>61.750</td>
</tr>
<tr>
<td>Not Attending (n=1)</td>
<td>62.000</td>
<td>65.000</td>
</tr>
<tr>
<td>Family Members</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attended (n=5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Attending (n=1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clients

- Mean: 64.000
- S.D.: 5.292
- Range: 59-70

Family Members

- Mean: 60.200
- S.D.: 10.498
- Range: 42-68

* Higher scores indicate a higher level of drug adherence. Possible range: 12-84.
Research Question 3. Were there differences between the schizophrenic client's and at least one family member's perception of the medication compliance behaviors following program attendance?

Medication Adherence Assessment Tool. Again, on comparison of the responses of clients and their family members on the MAAT (clients: n=5; family: n=5), there is little change in the completeness of the answers from T1 to T2. In general, clients tended to be more specific in their answers than were their family members. Four of the five clients listed their medication by name as well as the frequency with which they took their medication. Only one of the five family members was able to list the names of the medication taken. Three of the five could list the frequency with which the medication was taken. This held true for both time periods and despite the fact that four of the five clients lived with their family members.

Self-Report Predictive of Drug Compliance. A comparison of total scale scores at T1 and T2 for the Self-Report Scale Predictive of Drug Compliance (SSPDC) was done for clients and their attending family members. Again, because of the small sample size only frequency distribution comparisons were done.

The lowest total scale score for clients decreased from T1 to T2, while the highest total scale score increased for clients. This resulted in the previously
discussed slight decrease in mean total scale scores. This is in contrast to the lowest and highest total scale scores of family members which increased from T1 to T2. There was also an increase in the mean total scale score for family members from T1 to T2. However, the mean scale scores for T1 and T2 for both clients and family members were within five points of each other for both time periods, indicating both clients and family members perceived medication adherence similarly across groups (See Table 6).

Summary

The lack of adequate sample size precluded the computation of statistical procedures which would specifically address change differences. A visual comparison of responses to the MAAT and frequency distributions for the SSPDC indicated no difference from T1 to T2 on perception of medication adherence for all clients and attending family members.
CHAPTER V

Discussion of the Findings

This chapter will discuss the findings and limitations of the study, implications for nursing practice and recommendations for nursing research.

Findings of the Study

The results of this study indicated that family education had little effect on the medication adherence behaviors of the schizophrenic clients. However, because the sample size precluded the computation of statistical procedures which would specifically address change differences, these findings must be interpreted with caution.

Some changes were noted which should be further explored, as the findings partially supported Bandura's reciprocal determinism theory (1974) that a change in knowledge or cognitions results in a change in behavior. The greatest change across groups came with the family members of clients who tended to perceive an increased adherence to medication regimens on the part of their family member. On the Self-Report Predictive of Drug
Compliance (SSPDC) at T1 the scores ranged from 42-68 (S.D.=10.50), at T2 they ranged from 61-70 (S.D.=3.70), meaning that the variability of family members' responses decreased and were similar to clients' responses.

This may be, as other researchers have suggested (Falloon et al, 1987; Ingram 1987), because the family members want to perceive the clients as being more adherent in their medication taking behaviors than the clients perceive themselves in an effort to "normalize" them. However, this change in variability may also suggest that as a result of the education experience, family members were more aware of the symptomatology and medication taking behaviors and therefore, better able to cope with their schizophrenic relative.

Complete recent demographic figures are not available to compare the sample with the general client population at the facility used. However, ethnically, the sample (33% Hispanic, 33% Caucasian, and 33% Native American) had more Native Americans and fewer Caucasians than the clinic population. The clinic figures indicate a Native American population of 5% and a Caucasian population of 57% (La Frontera, 1991). In a larger sample it would be interesting to break out the adherence rate by ethnicity to see if there are any differences.

Of interest is the fact that in both this study and Ingram's (1987) original study, it proved easier to find
participants with family members who were willing to attend than it did to find participants who were willing to attend without family members.

A number of reasons could be posited for this fact. The majority of clients who attended with family members lived with those family members. Research has indicated that 50% to 70% of schizophrenics live with their families (Brooker, 1990; Smith & Birchwood, 1987). It may be that clients who were living with family members were more easily motivated to attend such programs because of the additional influence of those family members. Clients without family members had to rely on clinic personnel and their own interest and motivation to encourage them to attend. Since a deterioration in social and occupational functioning is a characteristic of schizophrenics, their disease may have made it difficult for them to attend such a program without external motivation.

It is also possible that since clients were contacted for attendance by clinic personnel, and the staff were aware that the study had to do with family influence on medication adherence behaviors, they inadvertently biased the sample with clients with family members.

At the time of the original study, the facility utilized included family members in its medication education groups routinely. Because of budget constrictions, they no longer do this. Feedback from
clinic personnel indicated that the group was very well received by family members, and staff was asked when more groups would be offered for families; thereby indicating that the trend from the previous study was supported: family members were enthusiastic about the opportunity to be included in psychoeducational programs for the schizophrenic member.

In summary, although the sample size was small, the general trend, noted in Ingram's study (1987), of an improved relationship between client's perceptions of medication adherence and family member's perceptions of medication adherence continued.

Limitations of the Study

Because of the small sample size, generalizations cannot be drawn from this study to other populations of schizophrenic clients and their family members. A sample size of at least 10 in each category (i.e. clients with family members, family members, and clients without family members) is generally the minimum advocated to test for significant differences (Polit & Hungler, 1983). The size of the sample also precluded doing reliability and validity checks on the instruments used, rendering results suspect. It can be predicted, however, failure of subjects to list dosages on the Medication Adherence Assessment Tools (MAAT) may be a fault of the instrument, since
dosages were not explicitly asked for and schizophrenics tend to respond very concretely to questions.

Possible reasons for the small sample size may be the upheaval in the mental health system in the community in general. With funding cuts and competition amongst agencies for the funding dollars, clients are frequently being shifted from one agency to another with a decrease in the consistency of their care. This agency had noted a marked decline in the number of severely mentally ill clients in their day treatment program over the last year associated with the decreases in funding (Personal Communication, P. Joyce, Feb., 1992). Apart from the questions this raises regarding the quality of treatment clients now receive, this also points to the need to use multiple sites in future studies to secure adequate data for research.

Additionally, while the educational portion of the program did last an hour, the explanations of consents and testing procedures and completion of the pre-test instruments occupied an additional hour. Given the short attention span of most schizophrenic clients, it would have been better to break the session into two parts, conducted on two different days. Another possibility would have been to approach each client individually on an earlier occasion to complete the explanation and signing of the consent form and the pretest instruments.
The medication education program contained a great deal of information packed into a limited time space. Learning may have improved by breaking the teaching sessions into shorter segments over several time periods. This would have allowed for more discussion, opportunities for role playing situations, and occasions for questions. It would also have allowed for some repetition and review of information over time, which would also facilitate learning.

Implications for Nursing Practice

While no direct implications can be drawn from the results of this study, inferred implications can be made. The enthusiasm with which the medication education group was met by family members implies a desire for more information and skills by those members. If recent research is correct, and appropriate family intervention does improve outcomes for schizophrenics (Falloon et al., 1987; Hogarty & Anderson, 1986; Leff et al., 1984), then nursing, with its historically holistic philosophy, should be at the forefront of planning and implementing these kinds of programs in an effort to optimally impact outcomes in these times of fiscal restraint. It is also imperative that nurses begin tracking outcomes of treatment programs, so that formative and summative evaluations can provide
information on programs with the most desirable outcomes for the least expenditure of resources.

**Recommendations for Nursing Research**

A number of recommendations for future research can be suggested as a result of this study. First it is suggested that this study be replicated using multiple sites in order to improve the likelihood of obtaining a sample large enough to test for significant differences and to obtain reliability and validity for the instruments. Such a sample could also identify demographic characteristic which seem to influence medication adherence behaviors and lead to the development of techniques that would enhance those behaviors in populations most at risk.

It is further recommended that similar research be done utilizing a series of groups over a period of time and a variety of teaching techniques to facilitate the learning and integration of the material. This study might be more longitudinal in nature, conducting follow-up assessments at a series of extended time intervals to determine the stability of family influence on the retention and integration of medication adherence behaviors.

In order to validate self-report findings of improved medication adherence behaviors, additional methods of measuring medication adherence need to be included in research. These might include personal or staff
observation of behaviors, periodic pill counts, and urine and blood test to determine therapeutic levels. Research using a qualitative methodology may more readily elicit clients' and family members' perceptions of medication adherence importance and behaviors, and thus provide the background information necessary to develop effective treatment programs.

**Summary**

Although this study provided inconclusive data regarding the effects of family participation in a medication information program on schizophrenic clients' medication adherence behaviors, it did suggest a number of avenues to be researched utilizing a variety of research techniques. The study also recommends that nurses take a more active role in developing and evaluating treatment programs for schizophrenic clients and their families.
DEMOGRAPHIC SURVEY

SID: ___________________________ Date: ____________________

INSTRUCTIONS: SELECT THE NUMBER OF THE ANSWER WHICH DESCRIBES YOU BEST.

___ 1. ARE YOU
   1. MALE
   2. FEMALE

___ 2. WHAT IS YOUR AGE?

___ 3. HOW WOULD YOU DESCRIBE YOUR RACE/ETHNIC BACKGROUND:
   1. BLACK
   2. HISPANIC/MEXICAN AMERICAN
   3. AMERICAN INDIAN
   4. ORIENTAL
   5. WHITE/CAUCASIAN
   6. OTHER (SPECIFY)

___ 4. WHAT IS YOUR MARITAL STATUS?
   1. SINGLE
   2. MARRIED
   3. SEPARATED
   4. DIVORCED
   5. PARTNER DECEASED
   6. OTHER (SPECIFY)

___ 5. WITH WHOM DO YOU LIVE NOW?
   1. PARENT(S)
   2. SPOUSE
   3. FRIEND
   4. ALONE
   5. RELATIVES
   6. RELIGIOUS ORDER
   7. GROUP OF SAME SEX
   8. GROUP OF BOTH OR OTHER SEX
   9. HALFWAY HOUSE

___ 6. HOW MANY CHILDREN DO YOU HAVE?

CONTINUE ON NEXT PAGE
7. WHAT IS YOUR CURRENT SOURCE OF INCOME?
   1. EMPLOYMENT
   2. UNEMPLOYMENT BENEFITS
   3. SOCIAL SECURITY (SSI OR SSD)
   4. VETERAN'S BENEFITS
   5. GENERAL ASSISTANCE
   6. RELATIVES
   7. NONE

8. HOW CLOSE DO YOU LIVE TO YOUR FAMILY NOW?
   1. LIVE WITH THEM
   2. WITHIN 1 MILE
   3. BETWEEN 1 - 20 MILES
   4. BETWEEN 20 - 100 MILES
   5. BETWEEN 100 - 500 MILES
   6. OVER 500 MILES
   7. LOST CONTACT

9. WHAT IS THE HIGHEST LEVEL OF SCHOOL COMPLETED:
   1. 8TH GRAD OR LESS
   2. SOME HIGH SCHOOL
   3. HIGH SCHOOL GRADUATE
   4. SOME COLLEGE OR TRADE SCHOOL
   5. COLLEGE DEGREE
   6. GRADUATE WORK
   7. GRADUATE DEGREE
   8. POST-GRADUATE WORK

10. WHAT IS YOUR (OR YOUR FAMILY MEMBER'S) DIAGNOSIS:
    1. SCHIZOPHRENIA, CATATONIC TYPE
    2. SCHIZOPHRENIA, DISORGANIZED TYPE
    3. SCHIZOPHRENIA, PARANOID TYPE
    4. SCHIZOPHRENIA, RESIDUAL TYPE
    5. SCHIZOPHRENIA, UNDIFFERENTIATED TYPE
    6. SCHIZOAFFECTIVE
    7. I DON'T KNOW
MEDICATION ADHERENCE ASSESSMENT TOOL

CLIENT QUESTIONNAIRE

SID: ___________________________ DATE: _______

INSTRUCTIONS: PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. WHAT MEDICATIONS ARE YOU NOW TAKING AT HOME:
   A. PRESCRIPTION (ORDERED BY DOCTOR)
   B. NON-PRESCRIPTION (ORDERED BY DOCTOR)

2. HOW OFTEN ARE YOU TAKING THESE MEDICATIONS?
   A. PRESCRIPTION
   B. NON-PRESCRIPTION

3. HAVE YOU CHANGED THE AMOUNT OR FREQUENCY OF PRESCRIPTION MEDICATIONS YOUR ARE NOW TAKING IN THE PAST MONTH?
   A. HAS THE FREQUENCY CHANGED? HOW?
   B. HAS THE AMOUNT CHANGED? HOW?

4. WHEN WAS THE LAST TIME YOU WERE HOSPITALIZED ON A PSYCHIATRIC UNIT?

5. WHEN LAST HOSPITALIZED, WERE YOUR MEDICATIONS CHANGED?
MEDICATION ADHERENCE ASSESSMENT TOOL

FAMILY QUESTIONNAIRE

SID: ___________________________ DATE:

INSTRUCTIONS: PLEASE ANSWER THE FOLLOWING QUESTIONS.

1. WHAT MEDICATIONS IS YOUR FAMILY MEMBER NOW TAKING AT HOME?
   A. PRESCRIPTION (ORDERED BY DOCTOR)
   B. NON-PRESCRIPTION (ORDERED BY DOCTOR)

2. HOW OFTEN IS YOUR FAMILY MEMBER TAKING THESE MEDICATIONS?
   A. PRESCRIPTION
   B. NON-PRESCRIPTION

3. HAS YOUR FAMILY MEMBER CHANGED THE AMOUNT OR FREQUENCY OF PRESCRIPTION MEDICATIONS HE/SHE IS NOW TAKING IN THE PAST MONTH?
   A. HAS THE FREQUENCY CHANGED? HOW?
   B. HAS THE AMOUNT CHANGED? HOW?

4. WHEN WAS THE LAST TIME YOUR FAMILY MEMBER WAS HOSPITALIZED ON A PSYCHIATRIC UNIT?

5. WHEN LAST HOSPITALIZED, WERE HIS/HER MEDICATIONS CHANGED?
SELF-REPORT PREDICTIVE OF DRUG COMPLIANCE

CLIENT QUESTIONNAIRE

SID: _________________________; DATE: _________________________

INSTRUCTIONS: PLEASE CIRCLE THE NUMBER WHICH BEST DESCRIBES YOUR RESPONSE TO YOUR MEDICATION.

<table>
<thead>
<tr>
<th>SCALE</th>
<th>NOT AT ALL</th>
<th>LITTLE</th>
<th>LESS THAN</th>
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<th>MORE THAN</th>
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1. I FEEL MORE NORMAL

[ ] [ ] [ ] [ ] [ ] [ ] [ ]

2. MY THOUGHTS ARE CLEARER

[ ] [ ] [ ] [ ] [ ] [ ] [ ]

3. I FEEL MORE RELAXED

[ ] [ ] [ ] [ ] [ ] [ ] [ ]

4. THE GOOD THINGS ABOUT MEDICATION OUTWEIGH THE BAD

[ ] [ ] [ ] [ ] [ ] [ ] [ ]

5. IT IS UP TO DOCTOR WHEN I STOP MEDICATION

[ ] [ ] [ ] [ ] [ ] [ ] [ ]

6. BY STAYING ON MEDICATION, I CAN PREVENT A BREAKDOWN

[ ] [ ] [ ] [ ] [ ] [ ] [ ]
7. I FEEL LIKE A ZOMBIE
   1 2 3 4 5 6 7

8. I FEEL TIRED AND SLUGGISH
   1 2 3 4 5 6 7

9. I TAKE ONLY WHEN I'M SICK
   1 2 3 4 5 6 7

10. IT IS UNNATURAL TO TAKE MEDICATION
    1 2 3 4 5 6 7

11. I DO NOT NEED MEDICATION ONCE I FEEL BETTER
    1 2 3 4 5 6 7

12. I AM PRESSURED TO TAKE MEDICATION
    1 2 3 4 5 6 7
SELF-REPORT PREDICTIVE OF DRUG COMPLIANCE

FAMILY QUESTIONNAIRE

SID: __________________________ DATE: ________

INSTRUCTIONS: PLEASE CIRCLE THE NUMBER WHICH BEST DESCRIBES HOW YOU THINK YOUR FAMILY MEMBER IS RESPONDING TO HIS/HER MEDICATION.

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</table>

1. HE/SHE FEELS MORE NORMAL

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

2. HIS/HER THOUGHTS ARE CLEARER

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

3. HE/SHE FEELS MORE RELAXED

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

4. THE GOOD THINGS ABOUT MEDICATION OUTWEIGH THE BAD

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

5. IT IS UP TO DOCTOR WHEN HE/SHE STOPS THE MEDICATION

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |

6. BY STAYING ON MEDICATION HE/SHE CAN PREVENT A BREAKDOWN

   | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
7. HE/SHE FEELS LIKE A ZOMBIE
   1 2 3 4 5 6 7

8. HE/SHE FEELS TIRED AND SLUGGISH
   1 2 3 4 5 6 7

9. HE/SHE TAKES MEDICATION ONLY WHEN SICK
   1 2 3 4 5 6 7

10. IT IS UNNATURAL TO TAKE MEDICATION
    1 2 3 4 5 6 7

11. HE/SHE DOES NOT NEED MEDICATION ONCE HE/SHE FEELS BETTER
    1 2 3 4 5 6 7

12. HE/SHE IS PRESSURED TO TAKE MEDICATION
    1 2 3 4 5 6 7
APPENDIX B

HUMAN SUBJECTS APPROVAL
February 7, 1992

Martha H. Henderson, R.N., B.S.
c/o Leanna Crosby, D.N.Sc.
College of Nursing
Arizona Health Sciences Center

RE: HSC A92.22 THE ROLE OF FAMILY PARTICIPATION IN A MEDICATION INFORMATION PROGRAM ON SCHIZOPHRENIC CLIENTS' MEDICATION BEHAVIORS

Dear Ms. Henderson:

We received your revised consent form for your above cited project. The procedures to be followed in this study pose no more than minimal risk to participating subjects. Regulations issued by the U.S. Department of Health and Human Services [45 CFR Part 46.110(b)] authorize approval of this type project through the expedited review procedures, with the condition(s) that subjects' anonymity be maintained. Although full Committee review is not required, a brief summary of the project procedures is submitted to the Committee for their endorsement and/or comment, if any, after administrative approval is granted. This project is approved effective 7 February 1992 for a period of one year.

The Human Subjects Committee (Institutional Review Board) of the University of Arizona has a current assurance of compliance, number M-1233, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made either to the procedures followed or to the consent form(s) used (copies of which we have on file) without the knowledge and approval of the Human Subjects Committee and your College or Departmental Review Committee. Any research related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

William F. Denny, M.D.
Chairman, Human Subjects Committee

WFD:rs
cc: Departmental/College Review Committee
APPENDIX C

SUBJECT'S CONSENT
SUBJECT'S CONSENT

TITLE: The Role of Family Participation in a Medication Information Program on Schizophrenic Clients' Medication Behaviors.

I AM BEING ASKED TO READ THE FOLLOWING MATERIAL TO ENSURE THAT I AM INFORMED OF THE NATURE OF THIS RESEARCH STUDY AND OF HOW I WILL PARTICIPATE IN IT, IF I CONSENT TO DO SO. SIGNING THIS FORM WILL INDICATE THAT I HAVE BEEN SO INFORMED AND THAT I GIVE MY CONSENT. FEDERAL REGULATIONS REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS RESEARCH STUDY SO THAT I CAN KNOW THE NATURE AND THE RISKS OF MY PARTICIPATION AND CAN DECIDE TO PARTICIPATE OR NOT PARTICIPATE IN A FREE AND INFORMED MANNER.

PURPOSE: I am being invited to participate in the above-titled research project. The purpose of this project is to find out if family member's participation in a medication education program influences schizophrenic clients' medication taking behaviors. This information will help nurses plan better treatments for people with schizophrenia.

SELECTION CRITERIA: I am being invited to participate because I have a diagnosis of schizophrenia or have a family member with a diagnosis of schizophrenia. I am 18 years old or older, I can read, write and understand English, and I am aware of who I am, where I am, and generally what is going on around me. Approximately 20 to 30 subjects will be enrolled in this study.

STANDARD TREATMENT(S): I am aware that the taking of medication is a part of the standard treatment for schizophrenia.

PROCEDURE: If I agree to participate, I will be asked to agree to the following: 1) Fill out three questionnaires prior to attending a medication information class, 2) Attend a specific medication information class at the Day Treatment Program at La Frontera that will last approximately 1 hour, 3) Fill out and mail in the questionnaires again approximately 2 months following the class. Completion of the questionnaires will take approximately 10 to 20 minutes.

RISKS: I am aware that there are no known risks for participation in this study.
BENEFITS: I am aware that the benefits possible for participation in this study may be an improved awareness of my medications, why I take them, and how I can cope with the side effects.

CONFIDENTIALITY: I am aware that my participation in this study will be kept confidential. My name and address will be kept separate from the questionnaires I fill out. The purpose for the investigator having this information is so that the follow-up questionnaires may be sent to me. I understand that the researcher, Martha Henderson, R.N., and her advisor, Terry Badger, Ph.D., will have the only access to this information. The list of names and addresses of the participants will be destroyed at the conclusion of the study.

PARTICIPATION COSTS: I understand that there will be no financial cost to me for participation in this program. My only cost will be of my time. I understand the medication education program will last approximately one hour. I further understand that I will be contacted to fill out follow-up questionnaires in approximately two months, which will take approximately 20 minutes.

FURTHER USE OF DATA: I understand that the principal investigator, Martha Henderson R.N., may choose to use the data obtained in this project in additional research projects.

LIABILITY: I understand that side effects or harm are possible in any research program despite the use of high standards of care and could occur through no fault of mine or the investigator involved. I understand that there are no known side effects to this study. However, unforeseeable harm may occur and require care. I understand that money for research-related side effects or harm, or for wages or time lost, is not available. I do not give up any of my legal rights by signing this form. Necessary emergency medical care will be provided without cost. I can obtain further information from Martha Henderson, R.N., B.S., at 741-2351. If I have questions concerning my rights as a research subject, I may call the Human Subjects Committee at 626-6721.

AUTHORIZATION: BEFORE GIVING MY CONSENT BY SIGNING THIS FORM, THE METHODS, INCONVENIENCES, RISKS, AND BENEFITS HAVE BEEN EXPLAINED TO ME AND MY QUESTIONS HAVE BEEN ANSWERED. I UNDERSTAND THAT I MAY ASK QUESTIONS AT ANY TIME AND THAT I AM FREE TO WITHDRAW FROM THE PROJECT AT ANY TIME WITHOUT CAUSING BAD FEELINGS OR AFFECTING MY CARE AT LA FRONTERA. MY PARTICIPATION IN THIS PROJECT MAY BE ENDED BY THE INVESTIGATOR OR BY THE SPONSOR FOR REASONS THAT WOULD BE
EXPLAINED. NEW INFORMATION DEVELOPED DURING THE COURSE OF THIS STUDY WHICH MAY AFFECT MY WILLINGNESS TO CONTINUE IN THIS RESEARCH PROJECT WILL BE GIVEN TO ME AS IT BECOMES AVAILABLE. I UNDERSTAND THAT THIS CONSENT FORM WILL BE FILED IN AN AREA DESIGNATED BY THE HUMAN SUBJECTS COMMITTEE WITH ACCESS RESTRICTED TO THE PRINCIPAL INVESTIGATOR, MARTHA HENDERSON R.N., OR AUTHORIZED REPRESENTATIVE OF THE MENTAL HEALTH NURSING DEPARTMENT. I UNDERSTAND THAT I DO NOT GIVE UP ANY OF MY LEGAL RIGHTS BY SIGNING THIS FORM. A COPY OF THIS SIGNED CONSENT FORM WILL BE GIVEN TO ME.

Subject's Signature ___________________________ Date _______________

INVESTIGATOR'S STATEMENT
I have carefully explained to the subjects the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form understands clearly the nature, demands, benefits, and risks involved and his/her participation is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

Signature of investigator ___________________________ Date _______________
Martha H. Henderson
741-2351
REFERENCES


