COMPLIANCE, MEDICATION KNOWLEDGE, AND LOCUS OF CONTROL IN END-STAGE RENAL DISEASE PATIENTS

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SUE ELLEN OCHSNER, B.S.

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The Graduate School

Texas Woman's University

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We hereby recommend that the thesis prepared under our supervision by Sue Ellen Ochsner entitled Compliance, Medication Knowledge, and Locus of Control in End-Stage Renal Disease Patients

be accepted as fulfilling this part of the requirements for the Degree of Master of Science.

Committee:

Grace A. Willard
Chairman
Estelle D. Kurtz
Barbara D'Adamo

Accepted:

Phyllis Bridges
Dean of The Graduate School

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CHAPTER I

INTRODUCTION

The person with end-stage renal disease faces a complicated, long-term treatment regime. In most instances, thrice-weekly hemodialysis treatments are mandatory to sustain life. The patient must adjust to the stresses of a chronic illness with a demanding mode of treatment.

Because the dialysis program is most frequently conducted on an outpatient basis, responsibility for adhering to the prescribed regimen outside of treatment rests with the individual end-stage renal disease (ESRD) patient. The gap between the regimen prescribed for the patient and that actually followed can vary. The problem of noncompliance in self-administered regimens is increasingly recognized by studies in a variety of settings.

Noncompliance is a complex problem, resulting from many interrelated factors. One factor could be an individual's belief about the effectiveness of his following prescribed recommendations. Internal-external locus of control (LOC) is a construct based on one's belief in the usefulness of his actions. An internally-controlled individual believes that he controls the outcomes which

occur in his life through his actions. However, the externally-controlled person expects that forces beyond his control, such as chance, luck, or powerful others, determine the outcomes in his life. If the patient sees his future as being externally controlled rather than his own actions having a direct effect on the outcome of his condition, he may not feel that his taking a medication will directly help him. This could lead to noncompliance. A belief in external control is sometimes found in patients with chronic disease (Goldstein and Reznikoff 1971).

In addition to LOC, other variables may affect compliance. An understanding of the treatment regime is necessary for the patient to follow recommendations. It is widely believed that understanding the prescribed program of treatment motivates the patient to adhere to the regimen.

If factors such as knowledge about the treatment and LOC affect compliance, they must be considerations in nursing management. In order to assist the patient in attaining his treatment goal, the nurse must look at the person in his total environment and find ways to encourage compliance. Evaluating the relationship of patient knowledge of the medication treatment and the role of an internal-external control system will assist the nurse in her approach to encourage the patient to assume his active role in the treatment program.

Statement of the Problem

The problem of this study was to explore the relationship of knowledge of phosphate-binding medication and locus of control to the medication compliance of the ESRD patient.

Purposes

The purposes of this study were:

1. To identify the knowledge of selected dialysis patients about the use of antacids in their treatment regime

2. To identify the locus of control of reinforcement of selected dialysis patients through their score on the Health Locus of Control Scale

3. To identify the medication compliance of selected dialysis patients with the antacid regime, as measured by serum phosphorus levels

4. To compare the knowledge of the compliant and the noncompliant groups

5. To compare the locus of control of the compliant and the noncompliant groups

6. To compare the knowledge of the internally- and the externally-controlled groups

Background and Significance

Control of the phosphorus level is essential to the well-being of the dialysis patient. An elevated plasma phosphate level contributes to parathyroid hyperplasia, erosion of mineralized bone, and soft tissue calcification (Black 1972). Reiss et al. (1970) demonstrated the role of phosphate in decreasing serum calcium and in increasing parathormone (PTH) secretion. In two studies, Goldsmith et al. (1970, 1975) demonstrated that osteitis fibrosa can be prevented or reversed by inhibiting increased PTH secretion.

Black (1972) stated that the prevention of bone disease in long-term dialysis patients remains under study. However, the control of serum phosphate at normal levels with the aid of phosphate-binding agents is one general principle of management that has been established.

Bricker (1969) explained that dialysis effects only a temporary drop in phosphorus level, which will again be elevated before the next treatment. Bricker (1969) and Schoolwerth and Engle (1975) stated that phosphorus can be maintained at a normal level through the administration of aluminum gels to bind the phosphate in food and eliminate it through the intestinal tract. But Goldsmith (1975) cited the drawback of some patients' unwillingness to

continue taking large doses of aluminum gels to control phosphorus absorption. The patient may find the medication distasteful or be intolerant to the aluminum compound.

Compliance with the antacid regime is essential to the control of serum phosphorus levels in the chronic hemodialysis patient. However, compliance presents a complex problem. It is determined by the interaction of several variables, including demographic, illness characteristics, and socio-psychological variables. Reviews of the general compliance literature reveal wide variations in the extent to which patients deviate from prescribed regimens. Marston (1970) cited 4 to 100 percent noncompliance in her review of compliance studies, while Rosenburg (1973) found 40 to 90 percent rates of noncompliance. Comparison of studies is not valid because of the variety of measurements of compliance, that is, subjective measures, such as patient report, contrasted with objective measures, such as a test for urinary excretion of a drug (Marston 1970). But identification of high rates of noncompliance do indicate a problem.

A variety of studies are related to the problem of preventing renal osteodystrophy in the hemodialysis patient. One specific study of medication compliance according to drug classification rated antacids as the classification of

highest noncompliance, 83.3 percent noncompliant (Closson and Kikugawa 1975). Reasons given by patients for omitting the medication included objectionable taste, inconvenience of liquids, cost, and questionable effectiveness of a medication that can be taken without a prescription. ESRD patients have also been assessed for compliance in relation to diet. Garron (1976) stated that the best dietary compliers were those having close relationships with loved ones. Blackburn (1977) found that dietary noncompliance was significantly related to increased length of time on dialysis. A variety of factors have been related to compliance in the literature.

One factor which could be related to compliance with a medication regimen is the patient's understanding of the regimen. But the literature relating compliance to understanding is inconclusive. Rosenburg (1973) stated that noncompliance is a direct result of the health team's failure to define and carry out the educational portion of the patient's treatment. Rosenburg (1971) and Hecht (1974) demonstrated increased compliance after the implementation of an educational prescription. In contrast, Marston (1970) cited the fact that knowledge does not always lead to compliance. Weintraub (1973), Tagliacozzo (1974), and

Sackett et al. (1975) found no association between compliance and knowledge of disease.

Personality characteristics form another factor which has been studied in relation to compliance. De-Nour and Czaczkes (1976) did a predictive, longitudinal study about the influence of patient's personality on adjustment to chronic dialysis. Compliance with diet was considered one major area of adjustment. Although dietary compliance was significantly predicted, less than 25 percent complied well with diet. Abuse of the diet was related to certain personality characteristics, including low frustration tolerance, acting out of aggression, introjection of aggression, denial of sick role, or excessive gains from the sick role.

Anger (1975) also addressed the psychological factors in hemodialysis; she saw the nurse as a facilitator of adaptation. One problem regarding adaptation to hemodialysis was the patient's perception of his illness. If the patient saw his future as externally controlled, he needed help toward an internal orientation. If he could not see his actions as having a direct effect on his condition, he might not be motivated to follow the prescribed treatment.

Anger's (1975) interpretation of control is built on the concept of locus of control. Internal-external locus of control (LOC) is a theory developed by Rotter (1966). LOC is assessed by whether one believes that events in peoples' lives occur through their own efforts and skills (internal control) or through outside forces, such as luck or fate (external control). The Health Locus of Control (HLC) scale relates control to health-oriented behaviors (Wallston et al. 1976).

Using the I-E scale, Goldstein and Reznikoff (1971) found a significantly greater extent of external orientation in hemodialysis patients, as compared with patients recuperating from acute illness. Gentry and Davis (1972) stated that 72 percent of eighteen dialysis patients showed a highly external orientation. Relating external orientation to compliance, Anger (1975) stated that external control could prevent the patient's adherence to the prescribed regimen.

In summary, the literature revealed that personality characteristics are related to compliance. But the HLC scale has not been studied in relation to compliance. Knowledge of the treatment regime has been studied in relation to compliance, and the reports in the literature have been inconclusive.

Hypotheses

For the purposes of this study, the following hypotheses were tested.

1. There will be no significant difference in the knowledge about phosphate binding medication in the compliant and the noncompliant groups

2. There will be no significant difference in the locus of control of the compliant and the noncompliant groups

3. There will be no significant difference in the knowledge of the internally- and the externally-controlled groups

Definition of Terms

For the purposes of this study, the following definitions were used.

1. End-stage renal disease (ESRD)--chronic renal failure, requiring hemodialysis

2. Renal osteodystrophy--refers to the skeletal abnormalities and bone lesions which may occur in ESRD. The three types which may occur are osteomalacia, osteitis fibrosa, and osteosclerosis

3. Compliance--cooperation with the antacid regime. It is measured by a mean phosphorus level of 4.5 mg/100cc. or less

4. Noncompliance--refers to nonadherence to the antacid regime. It is measured by a mean phosphorus level greater than 4.5 mg/100cc.

5. Internal-external locus of control--refers to the extent to which a person sees events in his life happening through his own efforts (internal) or from outside forces, such as fate or powerful others (external).

Limitations

For the purposes of this study, the following limitations were identified.

1. Dietary intake of phosphorus affects the serum levels. Although all the patients are instructed in a 60 gram high biological value protein diet with individual sodium restriction, there is no control over the actual intake of dietary phosphorus

2. Each patient's interpretation of his own medication and dietary adherence varies

3. There is no control over the dialysate calcium concentration

4. The small sample size from one geographic location being treated with currently available dialysis technology limits the generalizability of the findings

5. Compliance with a medication regime results as an interaction of multiple variables. This study is confined to knowledge of medication, locus of control, and demographic factors

6. There is no control over the information about phosphate-binding medication presented to the patient

Delimitations

For the purposes of this study, the delimitations were

1. The selected dialysis patients required antacid treatment for phosphate retention

2. The selected patients were not receiving other known treatment that would affect the phosphorus level. Examples are Vitamin D, calcium preparations, or parathyroidectomy

3. The selected patients were not debilitated by complications of treatment and/or disease

4. The selected patients have been on chronic dialysis for a minimum of three months

5. Dialysate calcium level was 5.5 mg/100cc.

Assumptions

The assumptions for this study were

1. Decreased renal function leads to decreased clearance of phosphates

2. Compliance with phosphate binding medication is one factor in controlling serum phosphorus at normal levels

Summary

Chapter I has presented an introductory description of the study, designed to explore the relationship of medication compliance to locus of control and medication knowledge. Chapter II presents a comprehensive review of the literature, including an introduction, a discussion of ESRD, renal osteodystrophy, determinants of noncompliance, compliance related to locus of control, compliance related to knowledge, and compliance in ESRD. Chapter III outlines the methodology of the study through a presentation of the procedure for collection and treatment of data. Chapter IV is an analysis of the data, and Chapter V includes the summary, conclusions, implications, and recommendations for further study.

CHAPTER II

REVIEW OF LITERATURE

Lesparre (1976) reported that the treatment of ESRD with chronic hemodialysis is growing at the rate of 10,000 new patients each year in the United States. A review of the literature revealed the magnitude of the problem of ESRD, with the prevention of renal osteodystrophy being one important aspect of the treatment of the ESRD patient.

Outpatient treatment of chronic illness has demanded an active role by the patient in the management of medication and diet. Compliance with the therapeutic regimen has been recognized in the literature as an important aspect of attaining the treatment goal. The following review of the literature has developed the problem of ESRD and renal osteodystrophy, determinants of noncompliance, the relationship of LOC and compliance, the relationship of knowledge of the therapeutic regimen and compliance, and compliance studies with ESRD patients.

End-Stage Renal Disease

When the kidneys can no longer function adequately to preserve the integrity of the internal environment, renal failure or ESRD ensues. ESRD has been recognized as a

"total body disease" (Bailey 1972). The derangements in fluid, waste products, and chemistry have ultimately been

> . . . reflected in the water that bathes each body cell. . . . The manifestations of this disorderly process present as a change of pH of body fluids, an excess in total body water, an accumulation of retained wastes, a derangement in normal chemistries, a deterioration in enzyme function, a disordered physiology, and a malstructured anateomy (Bailey 1972, p. 1).

The derangements of chronic renal failure have resulted from a variety of causative factors. Freeman classified the types of diseases that can cause chronic renal failure. The classifications were

1. Diseases of infection,
2. Hypersensitivity diseases,
3. Hypertensive cardiovascular disease,
4. Metabolic diseases,
5. Congenital disorders,
6. Miscellaneous causes, including obstruction, stone formation, injury, and toxemia of pregnancy (1972, p. 4-9).

Any of these problems could precipitate ESRD. During the past thirty years, treatment of ESRD with hemodialysis therapy has grown to become an accepted mode of treatment. Abel, Rowntree, and Turner performed the first successful dialysis on an animal in Baltimore, Maryland in 1913. After a suitable cellophane membrane was produced and heparin was developed, Kolff performed the first hemodialysis on a human being in 1954. However, the first long-term

hemodialysis program only became a reality in 1960 with the advent of the Scribner shunt (Bailey 1972).

Initially, these chronic treatment programs were available only to the wealthy or to the medically indigent because of the prohibitive cost. Selection of patients was also practiced because of the limited number of machines (Bailey 1972).

By 1971, 4,600 patients were dialyzed on a regular, chronic basis. That year 55,000 patients died of ESRD, and 7,500 of those patients were suitable candidates for chronic hemodialysis (Burton et al. 1971). With the advent of Social Security coverage for chronic hemodialysis in 1973, 11,000 dialysis patients were extended financial coverage (Social Security Administration 1977). The present rate of increase has been calculated at 10 percent per year. Future forecasting has projected sixty patients per million population to be accepted for treatment each year with an overall mortality rate of 10 percent per year (Pliskin et al. 1976). Treatment availability has greatly improved, and technological advances have improved the quality of treatment. Patients have learned to adjust to dialysis as a way of life, but complicating factors of this total body disease must be prevented.

Renal Osteodystrophy

Contrary to early clinical impressions, Papper (1971) noted that bone complications have been common in the hemodialysis patient. Strauss and Welt (1971) illustrated the disordered calcium and phosphorus metabolism of renal failure in the following explanation. In chronic renal failure, the decline in glomerular filtration rate paralleled an increasing serum phosphorus level. As glomerular filtration decreased, phosphate clearance also decreased. As a result of phosphate retention and Vitamin D resistance, decreased calcium absorption ensued. A decreased serum calcium stimulated PTH secretion, which led to resorption of bone and renal osteodystrophy.

To support this theory, Reiss et al. (1970) demonstrated that one gram of oral phosphorus resulted in a small decline in serum calcium, which mediated a 60 to 125 percent increase in PTH. Dialysis was a temporary help in ESRD, but phosphorus would again be elevated before the next treatment (Bricker 1969). Goldsmith, Arnaud, and Johnson (1975) showed that each time there was an increase in serum phosphorus due to the patient's failure to take aluminum hydroxide, a corresponding increase in PTH was precipitated.

Goldsmith et al. (1971) manipulated the serum phosphorus level by binding phosphorus with oral aluminum hydroxide and attaining a concentration of 6 mg/100 cc. or less. Following this manipulation of phosphorus, the dialysate concentration of calcium was increased to 8 mg/100 cc. Both manipulations led to a substantial decrease in PTH, with alleviation of bone pain when present. In addition, further bone complications were prevented. In a later study, Goldsmith, Arnaud, and Johnson (1975) further substantiated these findings.

Vitamin D metabolism has also been shown to be affected in ESRD, and Vitamin D has played an important role in renal osteodystrophy. Vitamin D analogues have been studied, and short-term administration has shown correction of hypocalcemia, improvement of intestinal absorption of calcium, improvement of calcium and phosphorus balance, and suppression of hyperparathyroidism. To date, these drugs have only been available for investigational use (Coburn and Brickman 1976).

The problem of renal osteodystrophy has been subdivided according to the type of bone lesion. Heptinstall (1975) and Papper (1971) cited three types of bone lesions in renal osteodystrophy--osteomalacia, osteitis fibrosa, and osteosclerosis.

Osteomalacia was caused by inadequate mineralization of bone tissue, partly due to resistance to Vitamin D. The patients with this problem sometimes experienced bone pain. X-ray revealed radiolucent lesions due to inadequate mineralization.

The treatment of osteomalacia has involved the administration of Vitamin D and calcium gluconate, with the attendant hazard of hypercalcemia. Treatment also entailed adequate control of serum phosphate through diet and aluminum hydroxide administration.

Osteitis fibrosa, a second type of bone lesion seen in renal osteodystrophy, has resulted from secondary hyperparathyroidism. Evidence on radiography revealed distal bone resporption and/or cyst-like lesions. Treatment has been aimed at decreasing PTH secretion by increasing the serum calcium. Parathyroidectomy has been necessary in severe cases. Goldsmith, Arnaud, and Johnson (1975) stated that osteitis fibrosa was the main component of the renal osteodystrophy seen in this country.

A third type of bone disorder that has been seen in ESRD patients has been osteosclerosis. Osteosclerosis has resulted in increased bone density, and the cause has not been fully understood. Evidence of the problem has appeared mainly in the lumbar vertebrae. Bailey described

the pathophysiology as ". . . an exaggerated osteoblastic response" (1972, p. 65) which may result from an increased phosphorus level.

In addition to these three main lesions seen in ESRD patients, Stanbury (1971) cited the additional problem of metastatic calcification. When the calcium x phosphorus product reached 70 to 80 mg/100cc., calcium phosphate could precipitate. In the skin, this has caused pruritis (Heptinstall 1974). But it has occurred in more vital areas, such as blood vessels, and precipitated more serious problems (Papper 1971).

Despite the danger of serious potential problems, renal osteodystrophy was identified as a common occurrence in ESRD patients. In autopsy studies of bone lesions, Papper (1971) reported the finding of osteomalacia in half of the patients and osteitis fibrosa in a third of the patients. Massry (1969) studied bone disease in dialysis patients. He reported radiological findings of bone disease in 18 percent of patients dialyzing less than a year, in 70 percent of patients dialyzing one to two years, and 92 percent in patients dialyzing over two years.

Prevention of bone disease has been an important priority in the management of dialysis patients. However, a precise formula to prevent the problem has not been

available. Factors to be considered in the prevention of bone disease have included

1. Adequate dialysis,
2. Phosphate control with diet and antacids,
3. Adequate dietary calcium,
4. Appropriate dialysate calcium,
5. Sufficient Vitamin D (Hemodialysis Manual 1971, p. 14).

The control of serum phosphorus through the administration of antacids has been an important aspect of preventing bone disease. Bailey (1972) described a side-effect of antacids as being the adsorption of phosphorus in the gut. Insoluble complexes were thus formed and excreted in the stool.

The chemistry involved the following equations:

$$Al(OH)_3 + 3HCl \rightarrow AlCl_3 + 3H_2O$$

$$AlCl_3 + PO_4 \rightarrow \underset{\text{(insoluble)}}{AlPO_4} + 3Cl$$

Bricker (1969) and Schoolwerth and Engle (1975) stated that phosphorus can be maintained at a normal level through the use of aluminum gels.

In addition to phosphate-binding medication, the serum phosphorus level was also affected by diet. Blackburn (1977) stated that control of the serum phosphorus level by rigid dietary restrictions made the diet excessively difficult for the patient. For that reason, many dialysis

facilities have relied more on medication than on diet. Schoolwerth and Engle (1975) also cited drawbacks of severe dietary restrictions of protein and phosphorus. Such strict dietary management decreased intake of calcium and of calories. This led to negative calcium balance and catabolism of body tissue.

Bailey (1972) and Goldsmith (1975) recognized the unpleasantness and the unwillingness of some patients to take large doses of antacids on a continuing basis. In the experience of Goldsmith et al. (1975), the use of Phos-Lo cookies, high potency Basalgel, capsules, or coated tablets also adequately controlled the hyperphosphatemia. These preparations were more acceptable to the patient than large doses of the liquid preparation. Compliance with the medication was necessary to prevent renal osteodystrophy.

Determinants of Noncompliance

Noncompliance has become recognized as a problem by the health professions. In a general review of compliance studies in a variety of settings, Marston (1970) cited a wide variation of 4 to 100 percent noncompliance. Rosenburg (1973) also reviewed a variety of studies, finding a 40 to 90 percent rate of noncompliance. Rosenstock (1975) summarized that studies showed an average of 50

percent noncompliance. This average rate of 50 percent noncompliance held true for taking simple medications, as well as for more complicated regimens which required life-style changes.

The reliability of noncompliance rates cited in the literature has been questioned because of the following restrictions in such studies.

1. Noncompliance rates may have been underestimated because the sample included only a cross-section of subjects under treatment at the time of the study. Thus, patients who have dropped out of the treatment program were not included

2. On the other hand, published studies may have overestimated noncompliance because of the tendency to publish bad news. Reassuring rates may not have been submitted or published so quickly

3. Studies have often been done in large clinical centers with strong research orientations. Such centers may have generated samples of nonrepresentative patients with unusual disorders. As a result, noncompliance patterns of unusual groups of patients may not have been typical of the general population

4. Many definitions of noncompliance and a variety of measurements have been used (Sackett and Haynes 1976)

Thus, a variety of limitations have reduced the generalizability of research findings.

In an effort to clarify the problem of noncompliance, a variety of possible determinants of noncompliance have been analyzed. Characteristics of the patient which may have influenced noncompliance included a variety of demographic variables. Sackett and Haynes (1976) reviewed studies relating demographic variables to noncompliance. Demographic factors seemed to have a greater effect on access to health care than on the compliance of patients under treatment. In regard to age, thirty studies found no relationship between age and noncompliance, while seven studies found greater noncompliance in older age groups. The majority of studies found no association between sex, education, socioeconomic status, marital status, race, or religion and noncompliance.

In a consideration of environmental and social factors, Gillum and Barsky (1974) focused on the importance of family encouragement to support compliance. Family instability or disharmony and living alone were associated with noncompliance. The authors recommended that the management of noncompliance include support for the family or significant others through the use of social service agencies, if necessary.

Characteristics of the treatment regimen itself have been related to noncompliance. In relation to duration of therapy, noncompliance has been found to increase with time on therapy (Charney et al. 1967, McKenny et al. 1973). Also, types of regimens which required extensive behavioral changes resulted in increased noncompliance (Collette and Ludwig 1969, Davis 1967). Thus, a passive regimen administered by health personnel was more easily followed than a recommendation that required a change in habits. New habits, such as taking medications, were adopted more easily than altering old behaviors, such as dietary habits.

Complexity of the medical regimen has been significantly related to noncompliance, with an increase in noncompliance corresponding to an increase in components of the regimen (Neely and Patrick 1968; Weintraub, Au, and Lasagna 1973). This finding may have been related to the degree of behavioral change required. In response to the fact that the therapeutic regimen itself may affect noncompliance, Gillum and Barsky (1974) suggested modes of managing noncompliance related to the therapeutic program. Involvement of the patient in planning the program was recommended. Also, educational programs that allow for active patient participation were suggested.

Other studies found that noncompliance was related to the medication ordered. Medication administered for long-term preventive purposes was an identified source of noncompliance. Gordis, Markowitz, and Lilienfeld (1969) reported a 64 percent rate of noncompliance with oral penicillin prophylaxis against rheumatic fever. Children and adolescents who were accompanied to the clinic by a parent were better compliers, perhaps reflecting more family support. The critical factor related to compliance in this study was the degree to which the parent felt the child was vulnerable to a preventable disease.

Vincent (1971) also studied the use of a long-term, prophylactic prescription, the use of eye drops to prevent glaucoma. She found that patients with correct information about the medication were significantly more compliant. Study recommendations focused on an educational approach by nurses to encourage compliance. However, it was suggested that nurses not provide just more information, but that a careful evaluation be made of what kinds of information would be helpful.

Patients who were following long-term antacid regimens for the treatment of peptic ulcers were studied during hospitalization. Roth and Berger (1960) found that a sample of ulcer patients with medication labelled and

available at the bedside took less than one-half of the antacid prescribed. Studies were recommended to determine the causes and methods of dealing with nonadherence to a prescribed regimen.

Closson and Kikugawa (1975) studied medication noncompliance according to drug classification. They rated antacids as the classification of highest noncompliance, 83.3 percent. Reasons given by patients for neglecting the antacid regimen included an objectionable taste, inconvenience of carrying liquids when away from home, inconvenient timing, and cost. Also, patients questioned the importance and the efficacy of a medication that could be purchased without a prescription. Patient education was recommended as a method to reduce noncompliance. Thus, studies have revealed that characteristics of the regimen itself can be factors in neglecting the prescribed therapy.

Characteristics of the illness also have contributed to nonadherence to the regimen. Blackwell (1973) cited noncompliance in illnesses which were chronic in nature. Recommendations of the study included identification of "at-risk" patients, thoughtful treatment planning involving the patient, and patient education. Stewart and Cluff (1972) further recommended that patient responsibility for medication be initiated prior to discharge from the hospital

and that patient education be done by the physician, the nurse, and the pharmacist.

Asymptomatic, chronic problems which require preventive therapy have been associated with noncompliance. Antihypertensive drug therapy has been prescribed in an effort to prevent the complications of uncontrolled hypertension. A study of the effect of propranolol on plasma renin levels and blood pressure control showed poor correlation between serum propranolol and daily dosage due to noncompliance (Briggs et al. 1975).

Some educational programs which were tailored to the individual needs of each patient reported success in preventive programs. McKenny (1973) reported a significant decrease in the noncompliance rates and significantly improved blood pressure control in twenty-five subjects with a pharmacist planned educational program. The study concluded that compliance probably improved because of association with a health professional who understood the patient's disease, respected him, and had time to discuss his questions and program.

In another antihypertensive program, Alderman (1975) found 81 percent of ninety-four patients had satisfactory blood pressure control after one year in a program which was set up in the patient's work situation and provided

continuous follow-up by nurses. Finnerty (1975) discussed Alderman's study and stressed the role of the nurse to provide motivation in long-term, preventive programs. He cited the nurse as being more capable of motivating patients than the average physician. Also, he urged special training programs for nurses, similar to coronary care unit training, to prepare nurses to function in the management of chronic disease.

In summary, characteristics of the illness, such as chronicity of the illness and long-term preventive therapy with medication, have been associated with noncompliance. Recommendations and conclusions have supported the use of planned educational programs to enhance adherence to therapy. Characteristics of the patient and characteristics of the regimen have also been discussed as determinants of noncompliance.

Locus of Control

The Health Belief Model has been developed and utilized as a predictor of compliance (Becker 1976). One principle underlying the Health Belief Model was the individual's expectation that his actions can result in a certain outcome. The belief that one could control outcomes in one's life was equated with internal control by Rotter (1966).

Rotter's theory of internal-external locus of control was based on the idea of reward of reinforcement of a behavior being dependent on whether the individual perceived the reward as being dependent on his behavior or independent of it. Thus, an internally-controlled person believed that events in his life occurred through his own efforts and skills. In contrast, fate, luck, or powerful others were seen as the outside controlling forces of the lives of externally-controlled persons.

Two aspects of the locus of control construct have shown relevance to the problem of compliance. Specifically, internally-controlled individuals have demonstrated more active information seeking in relation to problems (Seeman and Evans 1962), and have utilized information more actively to deal with their problems (Phares 1968). Therefore, it has been hypothesized that internally-controlled individuals would know more about their medication and comply with it more faithfully.

The literature has substantiated the expectation that internally-controlled persons would be more likely to follow a prescribed regimen. Internally-controlled individuals exhibited a greater tendency to seek information and to adapt behavior patterns which utilize that information to control their environment (Joe 1971). Davis

and Phares (1967) found that internally-controlled subjects actively sought information which would be useful in the future. Such a finding could have relevance for preventive regimens.

Phares (1968) explained the improved utilization of information. Internally-controlled individuals expected that reinforcement would follow because of their efforts. Therefore, they saw proper utilization of information as a means to reinforcement. Additionally, the use of internal control to affect outcomes in one's life was interpreted as an indication of greater compliance; the person recognized his responsibility for his well-being. On the other hand, the externally-controlled person has been interpreted as more compliant because of his response to the outside force of a medical authority figure (Lowery and DuCette 1976).

Blackburn (1977) found no relationship between I-E control and dietary compliance. Lowery and DuCette (1976) found greater disease control in internal diabetics at three years, but internal patients had significantly more problems at six years. Such inconclusive findings were explained by a compliance study of diabetics which found no correlation between following a prescribed regimen and actual control of the disease (Williams 1967). Thus,

I-E control has not been conclusively related to compliance in the literature.

Locus of control has been studied as a function of chronic disease. Individuals with chronic illness have exhibited a more external orientation. Goldstein and Reznikoff (1971) found a significantly greater external orientation in hemodialysis patients compared with patients recuperating from acute illnesses. Gentry and Davis (1972) reported that 72 percent of eighteen hemodialysis patients showed a highly external orientation, and I-E control was not related to length of time on dialysis.

An improved understanding of the role of I-E control in the health behavior of chronic hemodialysis patients has implications for nursing care. Anger (1975) cited the patient's perception of his illness as an element the nurse must understand in order to be a facilitator of adaptation for dialysis patients. If the patient sees his future as externally controlled, he must be helped toward an internal orientation. If he does not see his actions as having a direct effect on his condition, he may not be motivated to follow his regimen. Goldstein and Reznikoff (1971) recognized that if the patient believes his behavior is unrelated to the outcome of his condition, he may easily reject his responsibility in the health regimen. A

recommendation was made that the patient be aided in developing a more internal outlook.

Fearing (1975) specifically applied the recommendation of an internal approach to the problem of renal osteodystrophy. She suggested individualized teaching programs with feedback to the patient about blood chemistries. Thus, the patient would see that his following the medication regimen had a direct effect on preventing bone problems.

Knowledge and Compliance

Teaching programs have been recommended to increase the patient's knowledge about his therapeutic regimen. However, knowledge of disease and therapy have not been clearly related to improved compliance rates. Some studies have shown a positive association between knowledge and increased compliance. Marsh and Perlman (1972) demonstrated that understanding of congestive heart failure was significantly related to compliance with digoxin. The authors equated lack of understanding by some patients with neglect of patient education by the medical team. Also, educational level was related to compliance in Marsh and Perlman's study, indicating a communication gap between the patient and the physician. Patient teaching was recommended as an integral part of patient care, using

simplified teaching aids geared to the patient's social and educational level.

Concern about teaching efforts was also voiced by Tagliacozzo and Ima (1970). In a study of "knowledge of illness as a predictor of patient behavior," knowledge of illness was significantly related to continued attendance at clinic. Recommendations to enhance compliance focused on teaching efforts that dealt with motivating factors, as well as increasing knowledge of illness.

Watkins et al. (1967) found a positive association between knowledge about diabetes and self-management of the disease, although those who knew more were in overall poorer control. This finding agreed with Williams et al. (1967), who found that performing the prescribed therapeutic regimen for diabetes was not synonomous with control of the disease. Watkins et al. (1967) recommended educational interventions to eliminate misunderstandings and to motivate, re-instruct, and support the patient. These implications called for a coordinated educational effort between the physician and the nurse.

Although knowledge has been positively associated with improved compliance, some studies have found no association between the two variables. Sackett and Haynes (1976) rated compliance studies with methodologic scores.

A statistical comparison of these scores indicated that studies which showed no association of knowledge with compliance had greater methodologic soundness.

Weintraub, Au, and Lasagna (1973) found that knowledge did not improve compliance with digoxin. However, Weintraub (1975) cited the responsibility of the entire health team in assisting the patient to comply. The study designated the health team to be advisors, while patients control their own bodies and have responsibility for their own health. The nurse's role was seen as educator and reinforcer of the regimen.

In studying the effects of teaching on compliance, Tagliacozzo et al. (1974) found that nurse intervention with teaching in an outpatient clinic did not significantly affect compliance. However, additional observations revealed that nurse intervention did offer the patient improved criteria for judgments about his illness and for manipulation of his daily life in order to adapt to his illness. Opportunity for "catharsis" in extraneous areas may also have positively affected the patient's trust and susceptibility to influence. The study recommended that consequences of nurse intervention not be evaluated solely in terms of behavioral change, that is, significantly improved compliance.

The inconclusive evidence of the importance of patient understanding of disease and therapy has not discredited the need for patient education. Sackett et al. (1975) reported that increased knowledge by mastery learning did not improve compliance in hypertensive patients. The study concluded that acquisition of knowledge was insufficient to change behavior. However, Sackett spoke of the ethical obligation to inform patients. Patients cannot comply with a prescribed regimen unless they understand it. In addition to educational strategies, patient education programs must plan for behavioral strategies. For the hypertension program, the recommendations for behavioral strategies included blood pressure and medication charting by the individual and the tailoring of the regimen to habits and to daily schedules.

Neufeld (1976) agreed that knowledge acquisition alone provides insufficient foundation for a patient education program. In reviewing patient education programs, he found that program objectives often ignored attitude change, which can be essential to promoting compliance.

Individualized programs have resulted in the patient successfully assuming a more active role in his health care and in greater compliance. Hecht's (1974) results showed that an educational program greatly improved the accuracy of

tuberculosis patients' self-medication. Teaching was individualized, focusing on congruence between the drug regimen and the individual's lifestyle. Self-medication accuracy increased with greater amounts of teaching. The group receiving the greatest amount of teaching was instructed before discharge from the hospital, in the clinic, and at home visits.

Rosenburg (1971) reported significantly reduced readmissions of congestive heart failure patients, as well as increased overall functioning in activities of daily living after the implementation of an educational program. He recommended the use of an educational prescription or order sheet in the hospital, tailored to the individual's needs. In conclusion, it has been shown that knowledge has not been conclusively related to compliance. Educational programs which have been effective have dealt with behavioral strategies and attitude change, as well as providing information.

Compliance in ESRD

Adherence to diet has been one measure of compliance with ESRD patients. De-Nour and Czaczkes (1972) studied personality factors in chronic hemodialysis patients that caused noncompliance. Denial of the sick role was one factor related to dietary noncompliance.

Denial has been documented as a major defense mechanism used by ESRD patients in an effort to cope with the stresses of long-term hemodialysis (Short and Wilson 1969, Greenburg et al. 1973, and Wright et al. 1966). De-Nour cited the following four major stresses for these patients:

1. Loss or threatened loss of part of the body or body function.
2. Dependency on the machines and the medical team.
3. Threat of death, including the inability to plan a future.
4. Frustration of drives and their derivatives (1970 p. 208).

Denial has been employed by the ESRD patient to reduce stress. However, Cummings recognized denial as ". . . the most important psychological reaction" the health team must deal with in the dialysis patient because of its ". . . deadly potential" (1970, p. 74). Three important features of denial were identified.

1. Denial results in suppression and distortion of instructions

2. Denial leads the patient to believe that he is above the problems of other patients. Therefore, restrictions do not apply to him

3. Denial results in withdrawal from the responsibilities of being a dialysis patient

Even though denial has been seen as adaptive, these features have led to a destructive use of the mechanism by dialysis patients.

Goldstein and Reznikoff (1971) and Goldstein and Fenster (1973) related both denial and locus of control to the dialysis patients' attempts to cope and to reduce stress. Anxiety was reduced if the patient did not feel responsible for the illness or the treatment regime.

Both denial and locus of control have been cited as factors which could restrict the patient's participation in the treatment regime. One feature of the regimen, adherence to dietary restrictions, has been studied as a measure of the dialysis patient's adjustment to the treatment program. De-Nour and Czaczkes (1972) found 45 percent of forty-three patients abused their diets. The personality factors related to noncompliance were:

1. low frustration tolerance,
2. acting out,
3. denial of sick role,
4. excessive gain from the sick role,
5. suicidal behavior (1972, p. 341).

Psychotherapeutic interventions were recommended for the causes of noncompliance. However, no intervention was recommended for most cases of denial.

Blackburn (1977) also studied dietary noncompliance by three measures. Of the fifty-three subjects studied,

she found that 25 percent of the sample had inadequately controlled serum potassium levels; 40 percent of the subjects had inadequately controlled phosphorus levels; and 51 percent inadequately controlled their weight gains between treatments. As a result of this study, Blackburn recommended that further research be done in the area of motivational techniques to encourage hemodialysis patients to adhere more closely to the medical regimen. Garron (1976) developed a teaching program about renal dietary management in response to the problem of dietary noncompliance.

Following the prescribed regimen has also been linked to the patient's ability to understand. During the 1960's, there were limited numbers of machines available for hemodialysis therapy. Ability to adhere to the regimen was a criterion for selection for treatment, and level of intelligence was considered indicative of ability to understand and to comply (Borkman 1976). That this selection criterion was used was apparent in studies predictive of adjustment in which the mean IQ of patients was 115 (Sand et al. 1966). Cummings (1970) said that the high level of intelligence was not the important factor, but the patient's understanding of the regimen was necessary to adjustment to dialysis.

Borkman (1976) studied "the relationship of staff estimates of patient's intelligence and understanding to compliance." All the data collected were staff estimates on 82 percent of the 1967 dialysis population. One belief held by staff members was that understanding of the regimen was the critical variable in compliance.

Borkman stated "No research studies could be found that measure the patient's level of understanding of restrictions and of intelligence in relation to patient compliance to test this . . . belief" (1976, p. 386). Studies which would relate understanding of restrictions and intelligence to compliance were recommended because staff beliefs could act as a self-fulfilling prophecy similar to that found in education. Beliefs that could have important influence on the patient should be founded on empirical evidence of validity.

Summary

A review of the literature revealed inconclusive findings in studies relating compliance to understanding of the regimen and to locus of control. However, the belief that understanding is critical to compliance has been seen as a commonly held point of view. ESRD patients have also been identified as more external in orientation. The

literature recommended that a more internal outlook be encouraged in hemodialysis patients to encourage their active participation in the treatment program. But noncompliance has not been conclusively linked to an external orientation.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

This study was set up as a quantitative descriptive study. It sought to detect significant differences between patient compliance and the variables of knowledge of medication, internal-external locus of control, and demographic factors. Chapter III describes the following: setting of the study, population, description of the tool, procedure for data collection, and procedure for treatment and analysis of data.

Setting

The Tarrant County Nephrology Center in Fort Worth, Texas, a limited care outpatient dialysis center, was the setting for this study. Written permission was obtained from the agency, and permission was granted to identify the agency in the report (Appendix A).

The dialysis center has been operational for five years, expanding from an initial patient population of 6 to the present population of 138 patients. The patients received dialysis treatments two or three times per week for five or six hours, depending on their individual needs.

Each dialysis shift could treat a maximum of thirty-eight patients. The nursing staff consisted of a head nurse (R.N.), a team leader (R.N. or L.V.N.) for every ten patients, plus two team members per team (R.N., L.V.N., or technician). Additional technicians were responsible for machine maintenance.

For the convenience of the subjects, the test was administered during the dialysis treatments. The questionnaire was administered only when the patient was feeling well and experiencing no side-effects of the dialysis treatment.

Population

For the purposes of this study, a random sample of sixty patients was chosen from the eligible patient population of the Tarrant County Nephrology Center, Fort Worth, Texas. Random choice allows each member of the population an equal opportunity to be included in the study. It is a technique for overcoming problems which might bias the study (Treece and Treece 1973).

Initially, the eligibility of patients was determined by their conformance to the stated delimiations. One hundred twenty-three of the 138 patients were eligible for the study. Each eligible patient was assigned a number.

The table of random numbers was then employed to select the sample of participants (Treece and Treece 1973). In using this table, the point of entry on the table was randomly selected. The researcher closed her eyes and selected the point of entry. Subject selection then proceeded by using three-digit numbers, moving from left to right, and subtracting each number from a multiple of 123, the eligible patient population. This rendered the two-digit table effective for a population greater than 100.

Description of the Tool

The tool for this study (see Appendix B) consisted of the following components.

1. Demographic data
2. A test to measure the patient's knowledge about his antacid medication, which was developed by the researcher
3. The Health Locus of Control Scale (Wallston et al. 1976)
4. Serum phosphorus levels, which were obtained from the patient's chart

A form to record demographic data was utilized which included age, sex, race, marital status, level of education, number of people in home, person who helps with

medication and diet, and length of time on dialysis. These items have been utilized frequently in compliance studies (Sackett and Haynes 1976).

Next, a test was developed by the researcher to measure the patient's knowledge about his phosphate-binding medication. The original thirteen questions were pretested. The pretest is used as a method of establishing validity and reliability. Validity pertains to the relevance of the questionnaire to the data needed. Reliability refers to the precision or consistency of the questionnaire in gathering data (Abdellah and Levine 1965).

For the purposes of this study, the pretest was used as a source of establishing content validity for the medication section of the questionnaire. The pretest was also an opportunity to check the data collecting procedure for the remainder of the instrument. After agency permission was obtained, the pretest was carried out in a large, outpatient dialysis center. A group of five patients who met the criteria for the study were chosen from the list of patients who were dialyzing at the time of the pretest. Results of the pretest, plus recommendations of the five patients, the medical director, the nursing supervisor, and the patient education coordinator led to improvement of the questionnaire. As a result of this input, one question about

normal phosphorus laboratory values was eliminated as unnecessary information for the patient. Several phrases were reworded for clarification, and one response was changed to avoid confusion of similar sounding words.

The medication section of the questionnaire was further validated by a panel of experts in the renal field. A cover letter (Appendix C) and the questionnaire were presented to two faculty members, each with the degree of Master of Science in Nursing and with a renal specialty, and to the nephrologist medical director of the dialysis center. This panel reviewed the questionnaire for item construction and content validity. Minor revisions for clarification of wording and ease in reading were suggested.

The final medication section consisted of twelve questions. They were closed-end, multiple-choice questions. Only question 1 was a fill-in-the-blank, asking the name of the patient's antacid medication. Question 2 asked the best time of administration, since the action of this medication depends on it being taken when food is in the stomach, contrary to the ordinary use of antacids. Questions 3 and 8 were concerned with the action of the medication. Questions 6, 10, and 12 addressed the dietary implications of the phosphorus problem. Question 7 pertained to the side-effects of the medication, meaning constipation for

aluminum-based antacids and diarrhea for magnesium based antacids. Question 9 pertained to the subject's individual control of phosphorus. The response was compared to laboratory values from the chart.

The third section of the questionnaire was a scale for measuring locus of control. The instrument for measuring a general locus of control is a forced-choice scale developed by Rotter (1966). Rotter (1975) described the scale as a broad measure which permits prediction in a variety of situations, but with a low level of prediction for a broad variety of topics. A narrower or more specific scale was recommended for areas of specific interest.

An area specific measure for locus of control in health-related behavior, the Health Locus of Control (HLC) Scale, was developed by Wallston et al. (1976). The tool showed discriminant validity with the I-E Scale and test-retest reliablity. Although the scale has not been used with hemodialysis patients, Wallston et al. (1976) recommended it for health researchers.

For the purposes of this study, the HLC scale was employed. This tool was developed as an eleven-item Likert format scale. It measured the degree to which a person perceives the health events in his life as being under his control or controlled by fate and external forces.

The test was scored with six points per question, from strongly disagree to strongly agree. The scoring was toward the external extreme, with some statements presented internally and some externally.

The final component of the tool was the objective measure of compliance. The last three serum phosphorus levels were obtained from the patient's chart. This laboratory test was done routinely and consistently once a month. Therefore, the results were available at no additional cost to the subjects.

Procedure for Data Collection

After permissions from the Texas Woman's University Human Research Review Committee (Appendix D) and from the agency were obtained, data collection began. The questionnaire was administered at the Tarrant County Nephrology Center while the subjects were on dialysis.

Prior to administration of the test, written permission was obtained from each participant, using the Texas Woman's University written description form (Appendix E). Anonymity was assured to each participant. He was assured that he was free to participate or to refuse or to quit at any time. If the patient did not completely answer the questionnaire, it was discarded and not included in the data collection.

Because the subjects were on dialysis, it was anticipated that they would need assistance in filling out the tests. Also, it was anticipated that some patients would have difficulty in reading the questionnaire. For these reasons, the questions were read to all participants without any additional interpretation, and the responses were recorded. The patient received a score on the medication test and on the HLC scale.

In addition to the tests, the three most recent serum phosphorus levels were obtained from the patient's chart. Since each participant was assigned a number to facilitate random sampling, this number was placed on the tests to aid in the collection of laboratory data. Thus, interval data were utilized from laboratory measurements as a measure of compliance. To summarize, data collection included demographic data, a score on the medication test, a score on the HLC scale, and a mean phosphorus level.

Procedure for Treatment and Analysis of Data

In order to compare the compliant and the non-compliant groups, the subjects were divided into three groups according to the objective measure of mean phosphorus levels. The three most recent phosphorus results were

collected from the patient's chart. Phosphorus levels of 4.5 mg/100cc. or less equalled compliance. Elevated levels that were greater than 4.5 mg/100cc. equalled noncompliance.

The major statistic employed to test the hypotheses was the t-test. The test determined if there was a significant difference in the mean values of the knowledge of the two groups and of the HLC scores of the two groups at the .05 level of significance. The t-test is a parametric test used to test for a significant difference between the group means (Abdellah and Levine 1965). A parametric test assumes a normal distribution and demands interval measurement. A representative, large sample is also a requirement for parametric tests. A sample size of thirty is the statistical dividing line between small and large samples (Fox 1970).

The participants were also divided into internally- and externally-controlled groups by a median split of the HLC scores. The knowledge of these two groups was compared to test the third hypothesis.

In addition, descriptive statistics were used to present the data. The demographic variables were investigated for similarities and differences of the compliant and noncompliant groups by the chi-square test. The chi-square test may be used to determine significant differences

between two independent groups, involving measurement as weak as nominal scaling (Siegel 1956).

Summary

Chapter III outlined the methodology for this descriptive study of antacid compliance in patients with ESRD on hemodialysis. The setting of the study, the population, and the method of random sampling were discussed. The tool and the validation of the tool were described. Also, the procedure for data collection and for treatment of the data were summarized.

CHAPTER IV

ANALYSIS OF DATA

A nonexperimental study was conducted to explore the relationship between phosphate-binding medication compliance in the ESRD patient and two variables. These variables were knowledge about the medication and health locus of control. A closed-answer questionnaire was developed to measure knowledge of the phosphate-binding medication. The HLC Scale was used to measure I-E locus of control. In addition, the random sample was divided into compliant and noncompliant groups according to their serum phosphorus control over the past three months. Demographic data were collected to explore associations with compliance in addition to answering the primary research question. This chapter presents an analysis of the data gathered. Tables are used for the purpose of clarity in the presentation of data. An interpretation of the statistical evaluation is presented, followed by a summary of the findings.

Description of the Sample

A demographic description of the sixty subjects who participated in this study is presented in tables 1 and 2.

TABLE 1

DISTRIBUTION OF SELECTED SUBJECT CHARACTERISTICS
(N = 60)

Description	Number	Percent
Sex		
Male	32	53
Female	28	47
Race		
White	33	55
Black	24	40
Chicano	2	3
American Indian	1	2
Marital Status		
Single	8	13
Married	38	64
Divorced/Separated	11	18
Widowed	3	5
Education		
Eighth grade or less	14	23
Some high school	14	23
High school graduate	22	37
Some college	6	10
College graduate	4	7
Living Arrangements		
Alone	7	12
With others	53	88
Help with Medicines and Diet		
Help	29	48
No help	31	52

The average age of the subjects was 46.6 years, with a range of eighteen to seventy-four years. The number of years on dialysis was 1.9 years with a range of 0.25 to 7.0 years.

Fifty-three percent of the samples were males and 47 percent were females.

TABLE 2

DISTRIBUTION OF SUBJECTS BY AGE AND YEARS ON DIALYSIS (N = 60)

Description	Mean	Standard Deviation	Range
Age	46.6	13.6	18 - 74
Years on dialysis	1.9	1.4	0.25 - 7.0

Divided according to race, 55 percent were white and 40 percent were black. Three percent were Chicano, and 2 percent were American Indian. The majority, or 64 percent, of the sample was married. The education level ranged from less than eighth grade to college graduates. Twenty-three percent had some high school education and 37 percent were high school graduates. A majority, or 88 percent, of the sample lived with others. Forty-eight percent had help at home with their diet and medication.

Analysis of the Data

Sixty subjects participated in the study. In order to study variables related to compliance, the study sample was divided into compliant and noncompliant groups. The

average phosphorus level for the last three months was considered a compliant level if it was controlled within a normal range, 4.5 mg/100cc. or less. Noncompliance was defined by a phosphorus level greater than 4.5 mg/100cc. Table 3 presents the division into compliant and noncompliant groups according to serum phosphorus levels. The phosphorus levels of the compliant group ranged from 1.9 to 4.5 mg/100cc. with a mean of 3.7 and a standard deviation of 0.77. Twenty-nine of the sixty subjects, or 48 percent, comprised the compliant group. In contrast, 52 percent, or thirty-one subjects, were noncompliant. Their mean phosphorus level was 6.0 mg/100cc., with a standard deviation of 0.99 and a range of 4.6 to 8.2 mg/100cc.

TABLE 3

COMPLIANCE AND NONCOMPLIANCE BY PHOSPHORUS LEVELS
(N = 60)

	Number	Percent	$\bar{X}$	Standard Deviation	Range
Compliant	29	48	3.7	0.77	1.9-4.5
Noncompliant	31	52	6.0	0.99	4.6-8.2
Overall	60	100	4.9	1.42	1.9-8.2

Analysis of Demographic Data

The qualitative demographic variables were investigated for similarities and differences of the compliant and noncompliant groups by the chi-square test. For the demographic variables that were quantitative, the *t*-test was utilized.

Tables 4 through 11 present the demographic data according to compliance, along with the statistical comparisons. All comparisons were made at the .05 level of significance. By age (table 4), there was a borderline significant difference in the means, with p = .12. The compliant group was older, with a mean age of 49.4 years. The mean age of the noncompliant group was 43.9 years.

TABLE 4

COMPARISON OF GROUPS ON AGE
(N = 60)

	Number	$\bar{X}$	Standard Deviation	Age Range	*t*	p
Compliant	29	49.4	11.25	29-74	1.60	0.12*
Noncompliant	31	43.9	15.11	18-69		
Overall	60	46.6	13.56	18-74		

*Borderline significance.

This borderline difference was substantiated by a correlational procedure. The point biserial correlation test enables mixed data to be used when one variable is continuous and provides interval data and the second variable provides dichotomous data (Fox 1970). The point biserial correlation for compliance with age is 0.20 with a borderline significance of 0.12. This correlation indicates that as age increases, compliance with antacid medicine increases.

In concurrence with the positive correlation between age and compliance, there was also a borderline significant correlation between age and phosphorus level. The Pearson product-moment correlation coefficient was calculated. This statistic requires data on an interval scale, and it assumes a normally distributed population (Siegel 1956). The correlation coefficient was -0.23 with a probability of 0.07. This correlation was of borderline significance, agreeing with the previous correlation of age and compliance. Thus, as age increases, the phosphorus level decreases, indicating improved compliance.

The remaining demographic data were analyzed for relationships to compliance. There was no significant difference between the compliant and the noncompliant groups on years on dialysis (table 5). The noncompliant

group had received dialysis treatments for a somewhat longer period of time, with a mean value of 2.0 years compared to a mean value of 1.8 years for the noncompliant group.

TABLE 5

COMPARISON OF GROUPS ON YEARS ON DIALYSIS
(N = 60)

	Number	$\bar{X}$	Standard Deviation	Range in Years	t	p
Compliant	29	1.8	1.33	0.25-5.0	-0.68	0.50*
Noncompliant	31	2.0	1.46	0.25-7.0		
Overall	60	1.9	1.39	0.25-7.0		

*No significant difference.

Tables 6 through 10 reveal no significant difference between the compliant and the noncompliant groups for sex, race, marital status, educational level, and living arrangements. The data are summarized in the following tables.

TABLE 6

COMPARISON OF GROUPS FOR SEX DISTRIBUTION
(N = 60)

	Compliant		Noncompliant		Total	
	Number	Percent	Number	Percent	Number	Percent
Male	16	55	16	52	32	53
Female	13	45	15	48	28	47
Total	29	100	31	100	60	100

Chi-square = 0.08
Probability = 0.78
No significant difference

TABLE 7

COMPARISON OF GROUPS FOR RACIAL DISTRIBUTION
(N = 60)

	Compliant		Noncompliant		Total	
	Number	Percent	Number	Percent	Number	Percent
White	16	55	17	55	33	55
Black	11	38	13	42	24	40
Chicano	1	3.5	1	3	2	3
American Indian	1	3.5	0	0	1	2
Total	29	100	31	100	60	100

Chi-square = 1.13
Probability = 0.77
No significant difference

TABLE 8

COMPARISON OF GROUPS ON MARITAL STATUS
(N = 60)

	Compliant		Noncompliant		Total	
	Number	Percent	Number	Percent	Number	Percent
Single	5	17	3	10	8	13.3
Married	19	66	19	61	38	63.3
Divorced/ Separated	3	10	8	26	11	18.3
Widowed	2	7	1	3	3	5
Total	29	100	31	100	60	100

Chi-square = 3.04
Probability = 0.39
No significant difference

TABLE 9

COMPARISON OF GROUPS FOR EDUCATIONAL DISTRIBUTION
(N = 60)

	Compliant		Noncompliant		Total	
	Number	Percent	Number	Percent	Number	Percent
Eighth grade or less	5	17	9	29	14	23
Some high school	9	31	5	16	14	23
High school graduate	10	35	12	39	22	37
Some college	2	7	4	13	6	10
College graduate	3	10	1	3	4	7
Total	29	100	31	100	60	100

Chi-square = 4.07
Probability = 0.40
No significant difference

TABLE 10

COMPARISON OF GROUPS FOR LIVING ARRANGEMENT
(N = 60)

	Compliant		Noncompliant		Total	
	Number	Percent	Number	Percent	Number	Percent
Alone	3	10	4	13	7	12
With others	26	90	27	87	53	88
Total	29	100	31	100	60	100

Chi-square = 0.09
Probability = 0.76
No significant difference

There is a borderline significant difference between the compliant and the noncompliant groups with respect to having help at home with medications and diet (table 11). Fifty-nine percent of the compliant group have help at home and only 39 percent of the noncompliant group have help. The chi-square is 2.38 with a probability of 0.12.

Analysis of Data by Hypotheses

The data were used to test the stated hypotheses. The first hypothesis stated that there will be no significant difference in the knowledge about phosphate-binding medication in the compliant and the noncompliant groups. The section of the questionnaire (Appendix B) which

TABLE 11

COMPARISON OF GROUPS FOR HELP WITH MEDICINES AND DIET
(N = 60)

	Compliant		Noncompliant		Total	
	Number	Percent	Number	Percent	Number	Percent
Help	17	59	12	39	29	48
No help	12	41	19	61	31	52
Total	29	100	31	100	60	100

Chi-square = 2.38
Probability = 0.12
Borderline significance

established a score for knowledge about phosphate-binding medication was composed of closed questions and one fill-in, naming the medication. Each question was equal to 9 points, meaning a total possible score of 108 points. Table 12 compares the knowledge scores and compliance. The noncompliant group scored higher, with a mean score of 54 points and a range of scores from 27 to 90 points. The compliant group had a mean score of 48.3 and a range of scores of 12 to 99 points. There was no significant difference in the knowledge scores of the two groups, upholding the first null hypothesis.

TABLE 12

COMPARISON OF GROUPS FOR KNOWLEDGE SCORES
(N = 60)

	Number	$\bar{X}$	Standard Deviation	Range	t	p
Compliant	29	48.3	18.76	12-99	-1.13	0.26
Noncompliant	31	54.0	20.09	27-90		
Overall	60	51.3	19.51	12-99		

Pearson product-moment correlations of the knowledge scores with other numerical data revealed additional findings (table 13). There was a significant negative correlation of knowledge with age, looking at the entire sample of sixty. There was a correlation coefficient of -0.34 with an associated probability of .008. Thus, the older subjects had lower scores. This finding was borne out for both the compliant and the noncompliant groups, with a borderline significant difference.

Knowledge correlated positively with years on dialysis for the overall group (table 13). The correlation coefficient was .19 with a probability of .13. This was a borderline significant correlation. In contrast, the noncompliant group had a positive correlation of phosphorus levels with years on dialysis. A correlation coefficient of

.27 and a probability of .14 reveal a borderline significant relationship. Thus, the patient who has been on dialysis for a longer period of time may be exposed to more information about his medication and score higher. However, increasing phosphorus levels indicating noncompliance are associated with increased length of time on dialysis. This agrees with the finding in table 12, indicating a higher mean knowledge score for the noncompliant group.

TABLE 13

SELECTED PEARSON PRODUCT-MOMENT CORRELATION COEFFICIENTS

Variables	Correlation Coefficients	p
Age with knowledge Entire sample (N = 60)	-0.34	.008
Age with knowledge Compliant group (N = 29)	-0.30	.11
Age with knowledge Noncompliant group (N = 31)	-0.33	.07
Years on dialysis with knowledge Entire sample (N = 60)	0.19	.13
Years on dialysis with phosphorus Noncompliant group (N = 31)	0.27	.14
Years on dialysis with phosphorus Compliant group (N = 29)	0.001	.99

The second hypothesis stated that there will be no significant difference in the locus of control of the compliant and the noncompliant groups. Table 14 compares the two groups of HLC scores. The mean score of the compliant group is one point higher than the mean score of the noncompliant group, 37.3 points opposed to 36.2 points. There is no significant difference in the means of the two groups. The null hypothesis is thus accepted. There is no significant relationship of LOC score to compliance.

TABLE 14

COMPARISON OF GROUPS FOR HLC SCORES
(N = 60)

	Number	$\bar{X}$	Standard Deviation	Range	t	p
Compliant	29	37.3	7.43	21-54	0.56	0.58
Noncompliant	31	36.2	8.55	22-51		
Overall	60	36.7	7.98	21-54		

Further analysis of HLC data reveals an additional relationship. Although there was no relationship between age and LOC in the noncompliant group, there was a borderline positive relationship in the compliant group.

For the purposes of the third hypothesis, the sample was divided into internally- and externally-controlled

groups. The third hypothesis stated that there will be no significant difference in the knowledge of the internally- and externally-controlled groups.

The HLC scale is scored from 11 to 66 points on a Likert-format scale. Wallston, Maides, and Wallston (1976) classified healthy subjects with a score of 34.5 (median) or less as internally controlled and those above 34.5 as externally controlled. Using the same split as Wallston, Maides, and Wallston (1976), twenty-three subjects or 38 percent were internal, and thirty-seven subjects or 62 percent were external. Thus, ESRD patients showed a higher percentage of externally-controlled individuals than internally controlled.

Table 15 presents internal and external control in relationship to the knowledge scores. The mean score of the internally-controlled group was higher than the mean score of the externally-controlled group, 54 points opposed to 49.5 points. However, there was no significant difference at the .05 level. Therefore, the null hypothesis is accepted.

Pearson product-moment correlations reveal further interesting relationships within the external group (table 16). The variable, years on dialysis, is positively correlated with knowledge scores. The correlation

coefficient is 0.31 with a probability of .06. Thus, borderline significance of the relationship is established.

TABLE 15

COMPARISON OF INTERNAL- AND EXTERNAL-CONTROL GROUPS FOR KNOWLEDGE SCORES (N = 60)

	Number	Percent	$\bar{X}$	Standard Deviation	Range	t	p
Internal	23	38	54	21.97	27-99	58	.39
External	37	62	49.5	17.91	12-90		
Overall	60	100	51.75		12-99		

TABLE 16

SELECTED PEARSON PRODUCT-MOMENT CORRELATIONS FOR THE EXTERNAL GROUP (N = 37)

Variables	Correlation Coefficient	p
Knowledge with years on dialysis	0.31	.06
Knowledge with phosphorus	0.26	.12
Knowledge with age	-0.57	.0002
Age with phosphorus	-0.37	.02

Elevated phosphorus levels, indicative of noncompliance, also correlate positively with higher knowledge

scores. The correlation between phosphorus and knowledge is 0.26 with a borderline significance level of .12. In addition, increasing age is significantly related to lower knowledge scores. The correlation coefficient is -0.57 with a probability of .002. Age is also significantly correlated with phosphorus levels in the externally-controlled group. The older subjects have lower phosphorus levels, indicating better compliance. The correlation coefficient is -0.37 with a probability of .02. This is a significant difference at the .05 level.

Analysis of the Questionnaire

The noncompliant group scored higher on the average on the questionnaire, as summarized in table 12. Table 17 presents a breakdown of the knowledge scores by individual questions. Except for questions 1, 5, and 7, the noncompliant group scored higher on the individual questions. The questionnaire itself appears in Appendix B.

An analysis of the medication section of the questionnaire revealed that all of the patients were able to respond to question 1 by naming their antacid medication. This information was categorized into liquid or capsule forms of medication. The relationship of form of medication and compliance was analyzed by the chi-square test (table 18). Quite unexpectedly, there was a significant difference

TABLE 17

COMPARISON OF COMPLIANT AND NONCOMPLIANT GROUPS BY INDIVIDUAL QUESTIONS

	Compliant (N = 29)						Noncompliant (N = 31)						Overall (N = 60)					
	Right		Wrong		Don't Know		Right		Wrong		Don't Know		Right		Wrong		Don't Know	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Q_1	29	100	--	--	--	--	31	100	--	--	--	--	60	100	--	--	--	--
Q_2	20	69	8	28	1	3	23	74	6	20	2	6	43	72	14	23	3	5
Q_3	10	35	7	24	12	41	13	42	9	29	9	29	23	38	16	27	21	35
Q_4	10	35	7	24	12	41	11	36	10	32	10	32	21	35	17	28	22	37
Q_5	3	10	1	4	25	86	1	3	9	29	21	68	4	7	10	16	46	77
Q_7	19	66	1	3	9	31	15	48	6	20	10	32	34	56	7	12	19	32
Q_8	12	41	3	11	14	48	17	55	4	13	10	32	29	48	7	12	24	40
Q_9	9	31	9	31	11	38	15	48	10	32	6	20	--	--	--	--	--	--
Q_{10}	2	7	18	62	9	31	5	16	17	55	9	29	7	12	35	58	18	30
Q_{11}	17	58	6	21	6	21	21	68	7	22	3	10	38	63	13	22	9	15
Q_{12}	19	66	3	10	7	24	23	74	4	13	4	13	42	70	7	12	11	18

in the compliance of the liquid group and the capsule group, with the liquid group being more compliant. The chi-square value was 4.31 with a probability of .04.

TABLE 18

COMPARISON OF COMPLIANCE GROUPS FOR FORM OF MEDICATION (N = 60)

	Liquid		Capsules		Total	
	Number	Percent	Number	Percent	Number	Percent
Compliant (N=29)	19	66	10	34	29	100
Noncompliant (N=31)	12	39	19	61	31	100

Chi-square = 4.31
Probability = .04
Significant difference

Seventy-two percent of the subjects answered question 2 correctly, with only 5 percent responding that they did not know the answer. Thus, the greater majority of the patients knew to take the medicine when they have food in their stomach in order for the action of the medication to be most effective. Questions 3 and 8 were concerned with the action of the medication. Comparing the two groups, a higher percentage of the noncompliant group

answered these questions correctly, while a greater percentage of the compliant group did not know the answer.

Question 4, concerning the prevention of bone problems, was answered correctly by a nearly equal number of patients in each group, ten subjects or 35 percent of the compliant group and eleven subjects or 36 percent of the noncompliant group. A higher percentage of the compliant group did not know the answer. Question 5 was apparently too difficult, with most patients having no understanding of the parathyroid glands. Seventy-seven percent of the overall group did not know the answer and 7 percent responded correctly.

Questions 6, 10, and 12 pertained to the dietary implications of the phosphorus problem. Question 6 had three responses--they were meat, milk, and cheese. The responses were frequently confused with high potassium foods, and the patients had little information about phosphorus in foods. Eighteen percent of the overall group answered meat correctly, while 19 percent checked milk and cheese. Thirty percent of the overall group did not know that dairy products were related to the phosphorus problem (question 10), and 58 percent answered incorrectly. Seventy percent of the overall group answered number 12 correctly, perhaps because the yes or no choice was easier.

The main side effect of aluminum based antacids is constipation and the patients mainly chose that answer or "don't know" to question 7. Only 12 percent of the overall group responded incorrectly. Fifty-six percent answered correctly. A higher percentage of the noncompliant group (55 percent opposed to 41 percent) knew that the antacid medication was related to the phosphorus level in question 8. This is possible because patients with elevated phosphorus levels are more frequently counselled about the problem. A related factor in question 9 indicates that 48 percent of the noncompliant group knew that their serum phosphorus level was elevated, while 31 percent of the compliant group knew that their serum phosphorus level was normal. Sixty-three percent of the total group knew that the antacid could help prevent itching (question 11), a common problem for dialysis patients. For the twelve questions, the overall range of scores was 12 to 99 points out of a possible 108 points.

Summary

This chapter presented a demographic description of the sample. In addition to the demographic data, each participant had a knowledge score for questions related to the prevention of renal osteodystrophy, a HLC score, and an average phosphorus level. After the subjects were

divided into compliant and noncompliant groups according to serum phosphorus control, the major hypotheses were tested with the t-test for two independent samples. Although no significant differences were noted in the major hypotheses, correlation coefficients revealed several relationships which made the makeup of the groups and the outcome of the hypotheses more clearly understandable.

CHAPTER V

SUMMARY, CONCLUSIONS, IMPLICATIONS, AND RECOMMENDATIONS

This descriptive study was designed to explore factors related to medication compliance in the ESRD patient. This chapter summarizes the study and discusses conclusions, implications, and recommendations.

Summary

The problem of this study was to explore the relationship of knowledge of phosphate-binding medication and locus of control to the medication compliance of the ESRD patient. The purposes of the study were to identify the patients' knowledge about phosphate-binding medication and the patients' locus of control of reinforcement. In addition, the patients were divided into compliant and noncompliant groups, according to their serum phosphorus level. The two groups were compared according to knowledge scores and locus of control scores. Finally, the knowledge scores of the internally- and externally-controlled groups were compared.

The instrument utilized to test knowledge was a test developed by the investigator. The HLC Scale was used

to measure locus of control (Wallston et al. 1976). Also, three monthly serum phorphorus levels were obtained, along with demographic data. The medication section of the questionnaire was approved by a panel of three experts in the renal field. The HLC Scale had test-retest reliability and discriminant validity from Rotter's LOC Scale. The entire questionnaire was pretested with a group of five patients who met the criteria for the study.

The final questionnaire was administered to a random sample of sixty patients with ESRD. The subjects were divided into compliant and noncompliant groups, according to their serum phosphorus level. Then, the major hypotheses were tested with the t-test for independent samples to determine if there was a significant difference between the two groups. Additional analysis of demographic data utilized the chi-square test, the t-test, the point biserial correlation, and Pearson product-moment correlations. All comparisons were made at the .05 level of significance.

Three hypotheses were tested in this study. No significant difference was found in the two groups in knowledge about the phosphate-binding medication or in the HLC scores. In addition, there was no significant difference in the knowledge scores of the internally- and

the externally-controlled groups. Further analysis with correlation coefficients revealed several relationships which made the makeup of the groups and the outcome of the hypotheses more clearly understandable.

Conclusions

The results of this study indicate that noncompliance with medication regimen is a problem. Fifty-one percent of the sample were deemed noncompliant, as measured by an elevated serum phosphorus level. This rate of noncompliance is in agreement with other studies. Rosenstock (1975) cited an average of 50 percent noncompliance with therapeutic regimens, regardless of type of treatment program.

There was no significant difference in the compliant and noncompliant groups in the demographic factors of sex, race, marital status, educational level, living arrangements, or length of time on dialysis. However, the noncompliant group was younger than the compliant group. Sackett and Haynes (1976) reviewed studies relating demographic variables to noncompliance. The majority of studies found no association between demographic factors and noncompliance.

Noncompliance was greater in those patients who did not have help at home with their medications and their diet. This supports findings in the literature which indicate the

importance of the support of a significant other to enhance compliance (Gillum and Barsky 1974).

There was no significant difference in the two groups in knowledge about phosphate-binding medication. The literature relating knowledge and compliance has been inconclusive. A finding of no significant difference agrees with the findings of Tagliacozzo et al. (1974) and Sackett et al. (1975).

There was a significant negative correlation of knowledge with age. Thus, the older subjects had lower scores. Knowledge scores were higher in the overall group for those who had dialyzed for a longer period of time. This may be indicative that these patients had been exposed to more information over time, since no planned educational program was being utilized. Such information did not enhance compliance. To the contrary, in the noncompliant group, there was increased noncompliance in those who dialyzed for longer periods of time. Elevated phosphorus levels, correlating with increased length of time on dialysis, also agree with Massry's findings (1969). He reported radiological findings of bone disease increasing with length of time on dialysis, with indications of bone disease in 92 percent of patients dialyzing over two years.

LOC, measured by the HLC scale, was not related to compliance. The mean score of the compliant group was 37.3 points, as opposed to 36.2 points for the noncompliant group. There was no significant difference in the two groups.

The literature documents the fact that there are two sides to external control. The externally-controlled patient may believe that his behavior is unrelated to the outcome of his condition and reject his responsibility for the health regimen (Goldstein and Reznikoff 1971). On the other hand, he may respond to the medical authority figure as the outside controlling force and comply with the recommended regimen (Lowery and DuCette 1976). If both of these outcomes are possible, the externally-controlled patient could be equally represented in both the compliant and the noncompliant groups.

The compliant group was comprised of more externally-controlled and older individuals. These data are consistent with the idea that externally-controlled individuals may be more compliant.

Sixty-two percent of the subjects were classified as externally controlled, reflecting a higher degree of external control in the chronically ill (Goldstein and Reznikoff 1971). Internal control did not significantly

enhance knowledge about medication. The internally-controlled group scored higher, with a mean score of 54. The externally-controlled group had a mean score of 49.5. This was not a significant difference. This was contrary to expectations because internally-controlled persons have been shown to be more active seekers and utilizers of information (Davis and Phares 1967).

In the externally-controlled group, knowledge was greater with increased time on dialysis. Perhaps, some degree of the knowledge score of externally-controlled subjects was due to repeated passive exposure to information over a period of time and not due to their active seeking of information.

The externally-controlled group showed increasing noncompliance with higher knowledge scores. This could indicate that the externally-controlled person does not utilize information because he feels that he has no control over the outcome of his condition. On the other end of the external continuum, there was an older group who knew less about the medicine, but they complied with it, controlling their phosphorus levels. Again, the external force of the physician authority figure showed influence on the older age group. Since these externally-controlled subjects were compliant, it has been shown that external

control is not synonymous with noncompliance. The recommendation of Anger (1975) and Goldstein and Reznikoff (1971) to encourage an internal orientation in all patients to foster compliance must then be questioned.

A comparison was made of forms of medication, liquid or capsule. The twenty-nine patients taking capsules had significantly less controlled phosphorus levels, $p = .04$. This finding was definitely in contrast to the commonly held opinion, substantiated in the literature, that the capsules are equally effective and more acceptable to the patient (Goldsmith, Arnaud, and Johnson 1975).

The overall analysis of the questionnaire revealed a wide range of scores. It seemed that a patient's information might be related to the types of problems that he has experienced. Since there was no program to present all the patients with the same basic information and since the patients probably were frequently too uremic to retain initial information, the frequency of the "don't know" and incorrect responses was not surprising.

Implications

The findings of this study have implications for nurses in practice, administration, education, and research. In nursing practice, one must realize that knowledge alone is insufficient to promote compliance. One must include

affective objectives and be concerned about behavioral strategies in planning educational approaches. Rather than aiming for an internal orientation in all patients, one could enhance compliance by being knowledgeable about the patient's LOC. Then, plan an individual approach according to whether the patient is externally or internally controlled. In addition to considering LOC, education programs should present information on the patient's level of understanding. Including the family or significant others in some fashion can enhance compliance in self-administered regimens.

Nursing administration must recognize the responsibility for preparing the patient for self-care away from an institution and for continued support to the patient in his efforts. Appropriate programs which will enhance compliance should be planned with multidisciplinary input.

This study also has implications for nursing educators. Nursing students must become aware of the problem of noncompliance and of their role in enhancing compliance through nursing practice.

Nursing researchers should design and evaluate programs to enhance compliance. To date, compliance studies have in large part been carried out by other health professionals. Nursing researchers should join in the multidisciplinary approach to this problem.

Recommendations

Based on the findings of this study, the following recommendations for further research are suggested.

1. The study should be repeated with the sample restricted to a younger age group

2. Replication of this study should be done in a different geographic locality to enhance the generalizability of the findings

3. The study should be expanded to measure a broader base of knowledge, instead of focusing on one medication, and a broader measure of regimen compliance

4. A compliance study should be designed to present and evaluate an individualized, educational program on medications, overcoming the lack of control over information presented to the patient

5. With the available raw data from this study, discrete age groups should be identified in relationship to compliance

6. In addition to the nursing studies, the findings of this study suggest the need for a pharmacology study to compare the effectiveness and dosage requirements of liquid and nonliquid phosphate-binders.

Based on the use of the tool developed for this study, the following recommendation is suggested.

1. Question 5 should be deleted, as it was found to be difficult and unnecessary

APPENDIX A

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING
DENTON, TEXAS

DALLAS CENTER
1810 Inwood Road
Dallas, Texas

HOUSTON CENTER
1130 M.D. Anderson Blvd.
Houston, Texas 77025

AGENCY PERMISSION FOR CONDUCTING STUDY*

THE Tarrant County Nephrology Center

GRANTS TO Sue Ochsner

a student enrolled in a program of nursing leading to a Master's Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem:

The antacid compliance of dialysis patients as a function of locus of control and medication knowledge.

The conditions mutually agreed upon are as follows:

1. The agency (may) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) (may not) be identified in the final report.
3. The agency (wants) (does not want) a conference with the student when the report is completed.
4. The agency is (willing) (unwilling) to allow the completed report to be circulated through interlibrary loan.
5. Other: _____

Date 5/25/77

E. K. Olsen MD
Signature of Agency Personnel

Sue E. Ochsner
Signature of student

Mary A Willard
Signature of Faculty Advisor

*Fill out and sign three copies to be distributed as follows: Original - Student; first copy -- agency; second copy -- T.W.U. College of Nursing.

APPENDIX B

QUESTIONNAIRE

BIOGRAPHICAL INFORMATION

Age_____Sex_____Race_____Marital Status_____

What was the last grade you completed in school?_____

How many people live with you at your residence?_____

Does anyone help you at home with your medicines and diet?

_____. Specify who_____

How long has it been since your first dialysis?_____

DIRECTIONS: Fill in the answer or check the right answer.

1. What is the name of your antacid medication?_____

2. Antacid medication works best for the dialysis patient when taken:
   _____a. Between meals
   _____b. Any time
   _____c. Immediately before or during meals
   _____d. 30 minutes after meals
   _____e. Don't know

3. Although this medication is commonly taken to relieve excess acid in the stomach, dialysis patients take antacid medication to:
   _____a. Bind waste products
   _____b. Increase the blood count
   _____c. Bind calcium in food
   _____d. Bind phosphates in food
   _____e. Don't know

4. On a long-term basis, the medication can help prevent:
   _____a. Tingling in the feet
   _____b. Low blood count
   _____c. Bone problems
   _____d. Too much calcium
   _____e. Don't know

5. This medication also helps prevent:
   _____a. Increased thyroid activity
   _____b. Increased parathyroid activity
   _____c. Decreased parathyroid activity
   _____d. Decreased blood count
   _____e. Don't know

6. Check the foods which are high in the substance which makes this medication necessary: (More than one answer)

_____a. Meat	_____e. Oranges
_____b. Tomatoes	_____f. Coffee
_____c. Bananas	_____g. Cheese
_____d. Milk	_____h. Strawberries
	_____i. Don't know

7. The main side effect which may be caused by your antacid is:

_____a. Diarrhea	_____e. Dizziness
_____b. Constipation	_____f. Fainting
_____c. Nausea	_____g. Don't know
_____d. Vomiting	

8. The amount of antacid medicine which must be taken by the dialysis patient is adjusted by the:
   _____a. Serum calcium level
   _____b. Hematocrit
   _____c. Serum creatinine level
   _____d. Serum phosphorus level
   _____e. Don't know

9. What is your most recent blood level for this test?
   _____a. Normal
   _____b. High
   _____c. Low
   _____d. Don't know

10. Taking this medication faithfully permits the dialysis patient to enjoy more:
    _____a. Fruits
    _____b. Dairy products
    _____c. Fluids
    _____d. Vegetables
    _____e. Don't know

11. The antacid medication can help prevent itching, which is a common problem in dialysis patients.
    _____a. Yes
    _____b. No
    _____c. Don't know

12. If a dialysis patient eats extra cheese, he needs less antacid medication.
    _____a. Yes
    _____b. No
    _____c. Don't know

DIRECTIONS: Check the response which describes your feeling. There are no right or wrong answers.

	Strongly Disagree	Moderately Disagree	Somewhat Disagree	Somewhat Agree	Moderately Agree	Strongly Agree
	1	2	3	4	5	6
1. If I take care of myself, I can avoid illness.						
2. Whenever I get sick, it is because of something I've done or not done.						
3. Good health is largely a matter of good fortune.						

	Strongly Disagree	Moderately Disagree	Somewhat Disagree	Somewhat Agree	Moderately Agree	Strongly Agree
	1	2	3	4	5	6
4. No matter what I do, if I am going to get sick I will get sick.						
5. Most people do not realize the extent to which their illnesses are controlled by accidental happenings.						
6. I can only do what my doctor tells me to do.						
7. There are so many strange diseases around that you can never know how or when you might pick one up.						
8. When I feel ill, I know it is because I have not been getting the proper exercise or eating right.						
9. People who never get sick are just plain lucky.						
10. People's ill health results from their own carelessness.						
11. I am directly responsible for my health.						

APPENDIX C

1422 Ridgeview Drive
Arlington, Texas 76012
May 19, 1977

N. Kermit Olson, M.D.
Tarrant County Nephrology Center
1408 St. Louis
Fort Worth, Texas 76104

Dear Kermit:

As a graduate student in the College of Nursing at Texas Woman's University, I am currently involved in writing my thesis. I am requesting your assistance in validating my questionnaire.

The study will look at the relationship between medication compliance and the variables of internal-external locus of control and knowledge about the medication. I am specifically looking at the use of phosphate-binding medication in the dialysis patient's regime.

Please review my questionnaire about the antacid regime for content validity. The Health Locus of Control Scale on page 3 is a validated tool.

Thank you for your time and assistance.

Sincerely,

Sue Ochsner

APPENDIX D

TEXAS WOMAN'S UNIVERSITY
DALLAS, TEXAS 75235

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COLLEGE OF NURSING

June 8, 1977

Ms. Sue Ochsner
1422 Ridgeview Drive
Arlington, Texas 76012

Dear Ms. Ochsner:

The Dallas Center Sub-committee for Human Research has approved your proposal for "Antacid Compliance in Chronic Renal Failure as a Function of Locus of Control and Medication Knowledge." Following acquisition of agency approval, you may now proceed with your data collection as planned.

Sincerely,

Geri Goosen

Geri Goosen, R.N., M.S.
Assistant Professor/Coordinator
Graduate Medical/Surgical Nursing
Chairman of Human Research Committee

cc: Dr. Phyllis Bridges
Graduate Dean

GG:js

OFFICE OF THE ASSOCIATE DEAN
TEXAS WOMAN'S UNIVERSITY
DALLAS CENTER
1810 INWOOD ROAD
DALLAS, TEXAS 75235

OFFICE OF THE DEAN
TEXAS WOMAN'S UNIVERSITY
BOX 23026, TWU STATION
DENTON, TEXAS 76204

OFFICE OF THE ASSOCIATE DEAN
TEXAS WOMAN'S UNIVERSITY
1130 M. D. ANDERSON BLVD.
HOUSTON, TEXAS 77025

APPENDIX E

TEXAS WOMAN'S UNIVERSITY

(Form A -- Written presentation to subject)

Consent to Act as a Subject for Research and Investigation:

(The following information is to be read to or read by the subject):

1. I hereby authorize Sue Ochsner
(Name of person(s) who will perform procedure(s) or investigation(s)

to perform the following procedure(s) or investigation(s):
(Describe in detail)

This study is being done as a part of my requirements as a graduate student in nursing at Texas Woman's University. I am studying patient's understanding of their medication and attitudes about health problems in order to help plan more effective nursing care. I would like for you to complete a questionnaire, and I will take some laboratory information from your chart.

2. The procedure or investigation listed in Paragraph 1 has been explained to me by Sue Ochsner.
(Name)

3. I understand that the procedures or investigations described in Paragraph 1 involve the following possible risks or discomforts:
(Describe in detail).

The questionnaire will be read to you, but not interpreted for you. It will take about 20 minutes of your time on dialysis. You are free to participate or to quit at any time. Your identity will not be revealed in any way with the use of this information.

TEXAS WOMAN'S UNIVERSITY

(Form A - continuation)

3. I understand that the procedures and investigations described in Paragraph 1 have the following potential benefits to myself and/or others:

   Hopefully, this study will help nurses to more effectively meet patient needs in the area of self-medication.

4. An offer to answer all of my questions regarding the study has been made. If alternative procedures are more advantageous to me, they have been explained. I understand that I may terminate my participation in the study at any time.

_____ _____

Subject's signature Date

(If the subject is a minor, or otherwise unable to sign, complete the following):

Subject is a minor (age_____), or is unable to sign because:

Signatures (one required)

_____ _____

Father Date

_____ _____

Mother Date

_____ _____

Guardian Date

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