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SOCIOECONOMIC AND CULTURAL VARIABLES
INFLUENCING ESRD TREATMENT DECISION-MAKING

by

SUSAN AURA PFETTSCHER

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

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in the

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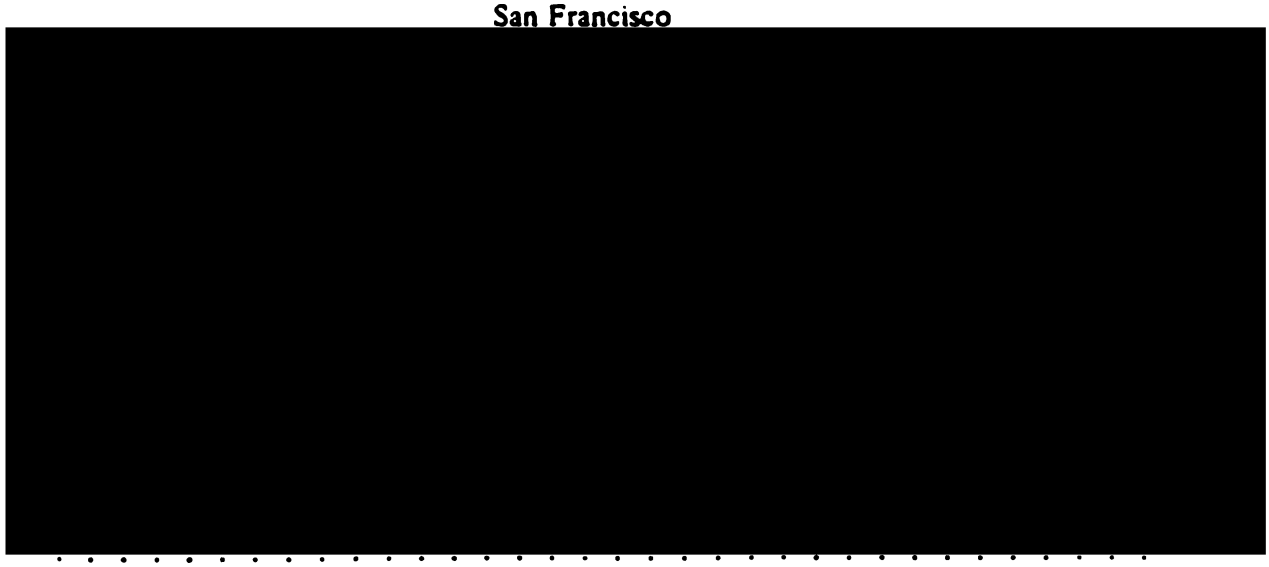

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by

Susan Aura Pfettscher

December 1991

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by

Susan Aura Pfettscher

ACKNOWLEDGMENTS

I wish to thank the 150 patients who participated in the interviews that made this research study possible. They gave unselfishly of their thoughts and feelings as they told me their stories. They all hold a special place in my heart.

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ABSTRACT

Patients with chronic renal failure are often confronted by decisions about undergoing treatment. In an attempt to identify whether any specific sociodemographic and economic variables influence this decision-making process, 150 adult patients who had initiated treatment via dialysis or kidney transplantation were interviewed. Using a semistructured interview technique, data was obtained to determine the process of decision-making and initiation of treatment for these patients.

The analysis of sociodemographic variables showed that the mean age of this sample is 60 years; gender distribution is 54% male and 46% female. Ethnic distribution is 60% White; 21% Black; 11% Hispanic; and 09% other. The majority of patients (63%) had a high school education or less. Half (50%) were retired while 22% were employed; 26% were receiving short or long-term disability at the time of interview while 3% reported themselves as unemployed. Sixty percent (60%) of this sample had an income level of less than $20,000/year. Fewer than half (46%) of the patients were married; 19% reported that they were widowed. A majority (71%) lived with a spouse or other family member.

While 97% of this sample had medical insurance, only 64% reported that they had been seeing a physician prior to their illness. Fifty-four patients (36%) indicated that they did not know of their renal failure prior to beginning treatment.

Patient's perception of choice of treatment modality (hemodialysis, peritoneal dialysis, renal transplantation) for renal failure can be predicted by the variables of age, income, and employment status based on logistic regression analysis. Only 54 patients in this sample reported that they felt they had a choice regarding treatment.

In summary, this sample identifies an older, more economically disadvantaged sample who are not routinely informed about treatment modalities for ESRD. The younger, single, employed patients reported that they felt they were informed about treatment and had a choice of modality.

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CHAPTER I

INTRODUCTION

Chronic kidney disease resulting in complete renal failure has been a fatal problem throughout recorded medical history. Persons who developed kidney failure died from the accumulation of fluid, excess electrolytes, and metabolic waste products in their bodies. Medical and nursing care were directed toward comfort and support during the terminal period of illness. As a nursing student, this researcher recalls caring for patients with chronic renal failure and uremia resulting in their deaths. During that time, some patients would return to the hospital multiple times for management of their symptoms and treatment with intermittent peritoneal dialysis. Within months of graduation from nursing school, this researcher had the opportunity to begin a career as a dialysis nurse providing hemodialysis treatments to selected patients to prevent their deaths from renal failure. Her continued career experience in caring for nephrology patients has led this researcher to undertake the study reported here.

This study examines the decision-making process that patients confronted with a diagnosis of chronic renal failure may undertake or experience as they make a choice of treatment modality(ies). In this area of specialized health care, the renal failure patients of today have several treatment options available to them; a number of variables may influence how an individual patient makes a decision about treatment modality. Of particular interest to this researcher are the socio-demographic, economic, and cultural variables which may impact on the

patient's decision-making process about treatment as well as how the patient's personal life and health experiences may influence decision-making. This research study is an attempt to measure these variables and their relationship to how the patient perceives his/her decision-making process. The study of the renal patient's decision-making process is significant as it is an essential and critical component of his/her informed consent for treatment.

Background to the Problem

Technologic advances in the 20th Century have been responsible for the successful treatment of chronic renal failure which previously resulted in the untimely death of its victims. The use of hemodialysis, peritoneal dialysis, and renal transplantation has maintained the lives of at least 372,000 patients for extended periods of time (U. S. Renal Data System [USRDS], 1990).

While not curing kidney failure, these treatments replace vital renal functions to a degree that allows people to live fairly normal lives including maintaining jobs, attending school, and continuing an active family and social life. People with kidney disease have exhibited their ability to adapt to their disease and its treatment, integrating the limitations that these create into their daily lives.

Treatment for End Stage Renal Disease (ESRD) is generally available throughout the United States with some geographic variations in distribution of dialysis and transplantation facilities. All patients undergoing regular dialysis treatment do so on an outpatient basis except when need for other medical care in a hospital setting is required. In 1988, there were 172,506 Medicare ESRD patients enrolled in the ESRD

Program (USRDS, 1990). This number is estimated to represent 93% of all ESRD patients in the U. S.; it did not include those who did not qualify for Medicare ESRD benefits, e. g., VA beneficiaries, active military personnel, Medicaid-only beneficiaries, or non-resident aliens. For patients who do not qualify for Medicare ESRD benefits, other medical payment programs may allow for patients to receive this life-saving treatment. However, there is no single data base or reporting system for the collection of inclusive data about all patients receiving ESRD treatment in the United States.

Through these various payment systems, ESRD treatment is essentially universally available to all persons in the U. S. without consideration of socioeconomic status, ability to pay, or presence of other medical conditions. This entitlement to care was legislated in 1972 via Public Law 92-603 which provided care to essentially all patients suffering from renal failure and thus prevented discrimination based on either medical or sociodemographic factors (Federal Register, 1976).

Prior to the passage of this legislation, ESRD treatment was not so readily available to all patients with kidney failure. Indeed, persons receiving treatment were selected based on their social status/worth, their economic circumstances, and their general excellent medical status of being young and otherwise healthy (Alexander, 1962; Scribner, 1972; Fox & Swazey, 1978).

This inequality of access to life-saving and sustaining treatment was considered morally unacceptable by American society; the passage of P. L. 92-603 was the result of massive efforts of health professionals, families and friends of patients, and elected officials to correct this unjust situation in health care access. To eliminate the problem of

financial constraints to care, payment for dialysis and transplantation via the already existing Medicare Program was included in this legislation. The implementation of this legislation has created a complex system of outpatient dialysis facilities providing regular treatments for ESRD patients, hospital facilities providing renal transplantation, and various bureaucratic agencies mandated to monitor the appropriate functioning of this program.

There are several unique features to this program and the care of ESRD patients which make it different from the delivery of other aspects of health care. These features of the ESRD Program include:

1. The only condition of vital organ failure which can be replaced by artificial technology in a clinically proven manner to prevent imminent death and maintain life for an extended period of time (e.g., 20 or more years).
2. The only disease for which government payment for treatment is available via the Medicare/Medicaid system for qualified recipients irrespective of other customary or selective criteria.
3. The only disease for which patients are guaranteed access to and choice of various treatments by federal laws and regulations without regard to cost or reimbursement constraints.

For these reasons, as well as many others, this program is representative of the technologic advances in medical care in the U. S., the bioethical dilemmas that exist in modern health care, and multiple health policy and economic issues in delivering clinically successful medical care. It also serves to exemplify many of the issues and processes of decision-making in health care, the physician and patient roles in such decision-making about treatment, and the role that the

organization of the health care system plays in this decision-making process.

Identification and Care of the ESRD Patient

Chronic renal failure (End Stage Renal Disease) is the result of a number of specific primary renal diseases or may be a complication of another primary disease or illness. No age, gender, or other social variables have been associated with the development of ESRD although there are different incident rates based on different ancestry. The United States Renal Data System (USRDS, 1990) reports that black and native American populations have a 3 to 4 times higher incidence rate of treated ESRD as compared to the white and Asian American populations. According to this report (USRDS, 1990), Diabetes Mellitus (Types I and II) is now the leading cause of ESRD while hypertension is the second leading cause.

Diagnosis and Treatment of Chronic Renal Disease

The physiologic changes that occur in renal disease/failure are well identified and described in multiple medical texts (Brenner & Rector, 1976; Drukker, Parsons, & Maher, 1983; Friedman, 1978). However, there is no single documentation of how the ESRD patient receives care or of how the U. S. health care system is organized to provide care for this specific disease state. The following is a synopsis of the observations of this nephrology clinical specialist/researcher over the course of her years of caring for patients with End Stage Renal Disease.

Because the symptoms of renal failure which may cause a person to seek medical care often develop late in the disease process, many persons are unaware of their renal disease until late in its course. The

diagnosis can be made early only in persons who are receiving routine medical care which would include routine blood studies. Progression of the complication of renal disease can be monitored in those patients who are receiving regular medical care for another primary illness (e.g., diabetes, hypertension). Reversal of renal damage is virtually impossible with current medical interventions although its progression may be stabilized or delayed with appropriate medical interventions and management. The problem of late diagnosis of renal disease may be intensified by the organization of the U. S. health care system which encourages utilization of service only at the time of symptomatic illness. Thus, patients may not know of their renal disease and its progression to end-stage until they need to begin replacement therapy. Other patients receiving regular medical care may be aware of their renal disease far in advance of requiring ESRD treatment.

The physician caring for the ESRD patient may have been providing care for an extended period of time before replacement therapy is required or he/she may initiate care of the patient at the time of diagnosis of ESRD. The renal physician (nephrologist) may be one of many physicians caring for the patient in this system of medical specialization. The patient may be receiving regular medical care from another physician and be referred for ESRD care only when the patient requires treatment. The private practice model which dominates outpatient health care in the U.S. minimizes contact with other health care personnel who might assist in the preparation of the patient for ESRD treatment with education, information, and emotional adjustment.

For the patient who is aware of his/her renal disease, who understands its steady progression to renal failure, and who is being seen

routinely by a physician, preparation for ESRD treatment is possible. In this circumstance, the patient can receive information about the treatment modalities available, make decisions about which treatment might be best for him/her, and receive the treatment which is best suited to him/her when it is necessary.

In this situation, the appropriate access device for dialysis can be surgically implanted in a timely fashion with a minimum of complications; renal transplantation can be carried out without need for dialysis treatment. Hospitalization can be minimized, and patient well-being is maximized by preventing the development of the uremic state which may include such complications as congestive heart failure, pulmonary edema, persistent nausea and vomiting, severe pruritus, and encephalopathy with seizures (Coe, 1976).

For patients who have been unaware of their impending renal failure, uremic symptoms causing clinical illness will develop requiring them to seek medical care via emergency physician or medical services. These patients generally require hospitalization for more extended periods of time frequently in the intensive care setting and often requiring invasive procedures to monitor their condition and to initiate emergent dialysis treatment. Because of their uremic state and acute illness, these patients may be less able to comprehend their illness and the need for continued treatment. Preparation for and choice of treatment modality is more limited because these patients cannot as easily participate in this process due to the acuity of their illness.

Review of Current ESRD Treatment Modalities

Hemodialysis remains the mainstay treatment for chronic renal failure. While technical advances in the equipment used for hemodialysis have been achieved, the principles remain those identified by Willem Kolff at the time he invented hemodialysis. The artificial kidney (the dialyzer) consists of a semi-permeable membrane which allows for the removal of end products of metabolism, excess electrolytes, and excess water from the vascular space of the body; technological advances in the structure of this membrane have allowed for increasingly efficient dialysis treatment in a reduced period of time (McBride, 1979). Currently, almost all patients undergo hemodialysis treatments two to three times per week for an average period of 3-4 hours per treatment; in earlier years, hemodialysis required periods of 10-12 hours per treatment performed 2-3 times per week.

The most current (1988) government data report that 83,410 patients were receiving chronic hemodialysis treatment in one of the 1712 outpatient centers in the U. S. and its territories. Only 2757 patients perform hemodialysis in their homes (with the assistance of a trained partner) while 1125 patients assist with their hemodialysis treatment (perform self-care) in an outpatient center (USRDS, 1990).

The systems for controlling the required extracorporeal blood flow through the artificial kidney, for mixing and delivering the dialysate solution required for diffusion and filtration of waste products and electrolytes across the semi-permeable membrane, and for monitoring all the critical components of the dialysis procedure have likewise become more sophisticated. Using microchip technology, current dialysis machines

are individually programmable and more controlled for fluid removal creating a safer and more efficient dialysis treatment.

Vascular access for hemodialysis uses either the technique of creation of an arteriovenous fistula in one of the upper extremities or the placement of an arteriovenous graft in either the upper extremity (upper or lower arm) or in the upper leg. In addition, "permanently" placed double lumen subclavian or jugular catheters can be used for weeks, months, or occasionally for years as a vascular access route for hemodialysis. One of the more frequent complications for patients undergoing hemodialysis is clotting or flow problems in these vascular access systems requiring declotting procedures, surgical repair, or replacement.

Peritoneal dialysis was actually the first type of treatment described and implemented for renal failure. Using technological advances, peritoneal dialysis has become a successful treatment modality for chronic renal failure/ESRD. Continuous ambulatory peritoneal dialysis (CAPD) as developed by Oreopoulas in the 1970's allows the patient to perform his/her own daily treatments without professional assistance (Oreopoulas, Robson, Izatt, Clayton, & DeVeber, 1978). The success of this treatment which uses the peritoneal cavity as the dialyzing membrane requires the instillation and subsequent drainage of a measured amount of dialysis fluid into and out of the peritoneal cavity via an implanted catheter approximately four times in a 24-hour period.

Patients who are taught to perform this modality require only simple mechanical skills and dexterity (sometimes with the assistance of various devices) and should have a willingness to perform these exchanges of solution on a regular basis using aseptic technique. In addition,

patients who cannot perform the procedure themselves can undergo CAPD by having someone else such as a spouse or other member of the household perform it.

An alternative to these intermittent exchanges performed during the day is available through the use of a machine which cycles the peritoneal dialysis fluid in and out of the body overnight while the patient sleeps thus eliminating the need for any dialysis exchanges to be performed during the day. The patient or a partner needs only to master the simple aspects of aseptic technique and simple machine operation and maintenance to undergo this variation of peritoneal dialysis.

These methods of peritoneal dialysis have been especially successful for persons who highly value their independence and freedom from a routine of frequent appointments at a dialysis facility. This treatment may also provide an viable alternative for patients who experience some physiologic complications of intermittent hemodialysis (e. g., cramps, hypotension, cardiac arrhythmias, or repeated vascular access failures) or who particularly find it difficult to conform to the dietary and scheduling restrictions often required for intermittent hemodialysis. For some patients, incidents of infections of the peritoneal dialysis catheter or within the peritoneum (peritonitis) make continuation of this treatment modality impossible.

From 1988 data (USRDS, 1990), 11,683 (7.9% of all dialysis patients) were undergoing continuous ambulatory peritoneal dialysis as their treatment modality; an additional 907 patients (0.9% of total) performed continuous cyclic peritoneal dialysis while another 2,328 patients were using an unspecified type of peritoneal dialysis.

Renal transplantation provides a treatment for ESRD that most closely resembles cure. The surgical implantation of a single functioning kidney provides adequate renal function to sustain life without need for dialysis treatment. While the immunological rejection of a transplanted organ remains the primary barrier to complete cure, current medications provide more specific immunosuppression with fewer side effects and complications to the patient. With this improved drug therapy, renal transplantation has become more available to patients who had been at higher risk of complications and to patients in a greater age range. A major limitation to renal transplantation is the availability of kidneys for transplant. The primary source of kidneys is from cadaveric donors who suffer brain death but whose kidneys remain viable at the time of pronouncement of death; these donors constitute a small group of young, healthy individuals who sustain a sudden irreversible insult or trauma primarily to the head (brain). This source has minimally increased (perhaps even decreased) notwithstanding the greater public and professional efforts and legislation directed toward recognition, referral, and consent for organ donation from this population.

The donation of a kidney by a genetically related adult (usually a sibling, parent, or adult offspring) provides a smaller number of transplants to ESRD patients; fewer living-related transplants are performed using kidneys donated by a more distant relative such as a cousin, aunt, uncle, or grandparent. An even smaller number of kidney transplants in the U.S. have utilized nongenetically related donors (someone who has an emotional relationship with the recipient, i.e., a spouse, very close friend, or significant other).

Data from the U. S. Renal Data System (USRDS, 1990) shows that 8882 patients received a kidney transplant in 1989; of this total, 1900 patients received a kidney from a living-related or living-unrelated donor while the majority (6982 patients) received a cadaveric donor transplant. The number of renal transplants performed yearly has remained essentially unchanged for the last 4 years while the number of ESRD patients awaiting a cadaver transplant has increased steadily during the decade of the 1980s to a total of 14,669 (USRDS 1990).

Social and Political Aspects of ESRD

From its early experimental period, the social and political aspects of dialysis and transplantation have been publicly expressed and debated. The public has followed the development of these life-saving technologies from the early media attention on the dramatic aspects of kidney transplantation to the agonizing decisions regarding selection of patients for dialysis treatment (Fox & Swazey, 1974, 1978; Alexander, 1962).

In an attempt to resolve the moral dilemmas created by these medical technologies, the Federal Government created the End Stage Renal Disease Program in 1972 via passage of Public Law 92-603 (Federal Register, 1976). This legislation provided for the payment for ESRD treatment via the Social Security/Medicare program. This entitlement program required that treatment be provided to anyone who needed it based on medical diagnosis regardless of age, race, sex, or socioeconomic status.

By virtue of Medicare regulations, this program is also extended to patients covered solely by state Medicaid programs. Thus, financial coverage is nearly universal for the delivery of ESRD treatment to U.S. citizens or residents. Program regulations require sharing of payment by

private health insurance programs if the patient has such coverage. Thus, patients are generally not denied ESRD treatment based on financial ability to pay.

In the nearly two decades since passage of this enabling legislation, the ESRD Program has allowed for tremendous expansion of dialysis and transplantation treatment.

Organization and Function of ESRD Facilities

The organization of facilities providing ESRD care is varied. While hemodialysis was originally provided in hospitals, the majority of facilities today are free-standing, proprietary facilities. The 1990 USRDS report (USRDS, 1990) noted that the growth of such facilities is at a rate of 7.1% per year and that approximately 53% of all dialysis patients were being treated in free-standing, for-profit facilities at the end of 1989. Fewer hospitals provide chronic outpatient treatment; only 18.8% of ESRD patients were being treated in hospital-based dialysis units at the end of 1989 (USRDS, 1990). These hospitals are often public facilities whose mission is to provide treatment to the indigent population. University health care facilities may also provide ESRD services within the context of their mission of teaching and service.

Renal transplantation remains an inpatient procedure provided by all types of hospitals (public, private, community, university); from 1981-1989, renal transplant programs have increased from 156 to 219, a 4.3% growth rate (USRDS, 1990). It would appear, therefore, that these programs are performing fewer transplants per facility given the lack of increase in the number of transplants performed over the past several years (as reported in a previous section).

Facilities may choose to provide both methods of dialysis--hemodialysis and peritoneal dialysis--to the patients it serves; however, there is no regulatory mandate to provide all modalities of dialysis treatment in a facility. More recently, facilities have been opened which provide only peritoneal dialysis training and followup care. The organization of these facilities is dictated not only by community needs and the philosophical commitment of health care professionals but also by considerations of financial profit (Starr, 1982; Plough, 1986).

Facility hemodialysis is provided by trained staff including registered nurses, licensed vocational nurses, and unlicensed hemodialysis technicians. Social workers and dietitians are also members of the facility staff. Each facility has a designated medical director and each patient receives continuing care from a practicing physician who is most often, but not necessarily, a board certified nephrologist.

As specified in the ESRD Regulations, all facilities receiving Medicare and/or Medicaid reimbursement for dialysis treatment undergo inspection and receive certification by the appropriate state and federal agencies (Federal Register, 1976). Hospital facilities also are reviewed via JCAHO certification.

Because California no longer has an organized method of health care planning and concomitant certificate-of-need system to determine community need for ESRD services, the geographic distribution of ESRD facilities is dependent on a competitive or market economy. Any individual or corporation who wishes to do so can build and operate a dialysis facility; the only regulation is that the facility meet the structural and operational regulations of the California Department of Health Services and the U. S. Department of Health and Human Services if it is to serve as

a Medicare and/or Medicaid provider. In northern California, 85 outpatient hemodialysis facilities operate in both metropolitan and rural areas often quite competitively in a single community; facilities may be located within blocks or a few miles of each other (ESRD Network 17, 1991). Most patients in metropolitan or suburban areas, therefore, do not have to travel long distances to a dialysis unit; however, patients may choose or be required to travel past other facilities to reach the center where their physician practices or where there is available space. Outpatient facilities may be open 6 days/week from early AM to early or late PM (depending on patient census) to provide care to three or four groups of dialysis patients in a single day; patients generally receive 3 times weekly treatment on a M/W/F or T/Th/S schedule. Such schedules may or may not be the most convenient for or meet the specific needs of the patients undergoing care in that facility.

Inpatient dialysis services are generally separately organized from outpatient facilities. Most hospital facilities offer inpatient hemodialysis treatment performed either by members of their own nursing staff who are specially trained to perform this treatment or through contracts established with facilities or agencies which provide nursing staff to perform dialysis treatments in the hospital. The relationship between these two services and agencies may be very cooperative and shared or there may be little, if any relationship and/or communication between these inpatient and outpatient services; minimal reporting of patient status to the staff of the outpatient facility is required at the time of patient discharge from the hospital to the outpatient facility.

Financial Aspects of Patient Entry into the ESRD Program

The patient who is discharged from the hospital with renal failure requiring continued outpatient treatment officially becomes an ESRD patient and can apply for Medicare ESRD benefits for payment of treatment. Similarly, the patient who does not require hospitalization as ESRD treatment is initiated becomes an ESRD patient at the time of his/her first dialysis treatment. A patient who receives a kidney transplant without dialysis being performed may become an ESRD Medicare beneficiary on the date of transplant.

Without regard to socioeconomic status (income and/or personal financial assets or holdings), patients may qualify for Medicare coverage if they have paid 10 quarters into Social Security (FICA) or if they are beneficiaries via their marital or parental status (USDHHS, 1989).

The HCFA form 2728, Evidence of End Stage Renal Disease, (Appendix A) which is completed by the physician and signed by the patient reflects the date of the first outpatient ESRD treatment (or renal transplantation) and serves as the patient's "application" for ESRD Medicare benefits. Currently, Medicare payment (in conjunction with other medical insurance or benefits) will not begin until 3 months after the date indicated on HCFA Form 2728 for the patient undergoing outpatient hemodialysis; for patients undergoing renal transplantation, home hemodialysis, or peritoneal dialysis, eligibility for benefits accrue from the date of first treatment. The intricate nature of Medicare coverage and reimbursement as related to specific treatment modality may have major implications for the patient's medical costs as ESRD treatment begins. In particular, initiation of treatment with a home treatment modality or with renal transplantation may allow for Medicare benefits to begin at the

initiation of treatment if the patient has no other medical insurance or whose insurance excludes treatment for renal failure because it is a prior condition or pre-existing illness (Federal Register, 1976).

Medicare Parts A and B will be available to those patients who qualify for coverage. These patients will be required to make the monthly copayment of the prevailing rate. For patients who already have Medicare benefits (by virtue of age or state of disability), application for specific ESRD coverage must still be completed.

If the patient has private medical insurance, it will also be used for payment of ESRD treatment. Currently, private medical insurance will pay 80% of charges in the first year with Medicare paying the remaining 20%; because treatment reimbursement is established by HCFA, charges for treatment and reimbursement amounts are relatively fixed. Currently, after the first 18 months of treatment, the percentage of payment reverses with Medicare becoming the primary payor (80%) with the private insurer paying (20%) (Federal Register, 1976).

In regard to private medical insurance coverage, there remains no mandate for inclusion of coverage of ESRD treatment. As previously noted, private health care insurance may exclude coverage for ESRD treatment as a prior condition or pre-existing illness. In addition, some plans or programs with preferred provider arrangements serve to limit patient access to choice of treatment facilities (both dialysis and transplant centers). Finally, coverage may restrict the patient's choice of treatment by covering only specific treatment modalities. The increasing diversity and complexity of coverage by private health care insurers requires expert individual assessment to ensure patient benefits and payment for treatment.

For patients without private medical insurance, Medicaid coverage may be available to them; these plans are dependent on the patient's financial assets and income. Medicaid may serve as a supplement to ESRD Medicare benefits or may provide the sole insurance coverage for ESRD treatment. Spending down may be necessary to qualify for benefits and/or the patient may have a financial liability or share-of-cost to pay. Medicaid regulations for ESRD coverage vary from state to state in regard to patient qualifications.

For medically indigent patients who do not qualify for either Medicare or Medicaid, treatment is generally provided by those facilities dedicated or contracted to provide such care; these facilities are most frequently county hospitals. ESRD payment for the medically indigent also varies from state to state and from county to county within the state depending on the organization of health care services. There have been no official reports about denial of treatment to such patients although it may well be the practice in some communities or facilities.

As noted previously, other small groups of patients including those with VA medical coverage or CHAMPUS coverage who do not qualify for Medicare benefits are often limited to receiving treatment only in specified facilities; contracting for treatment elsewhere is sometimes arranged for these patients.

Out-of-pocket expenses for patients with full coverage by Medicare and private health care insurance have not been quantified or documented in any formal way. The major costs that patients continue to experience are for prescription medications as these are not included in the Medicare reimbursement. The only exceptions to this regulation are coverage for two drugs--Cyclosporine, an immunosuppressive drug administered after

kidney transplantation and Epogen®, a synthetic form of erythropoeitin administered to treat the anemic state caused by renal failure. If the ESRD patient has medication coverage via private insurance or the Medicaid program, their medication expenses are also minimized. Personal expenses of travel to and from the dialysis facility are not reimbursed, dialysis treatments in another state may not be reimbursed by the patient's private insurer or Medicaid; dialysis treatments outside of the U. S. and its territories are not reimbursed by Medicare and may or may not be reimbursed by private insurers.

The individual patient may find some of these variables in reimbursement more or less important to his/her life with ESRD treatment. Obtaining information about this aspect of ESRD treatment and being able to understand the intricacies of these medical expenses and reimbursement may be difficult or impossible for the patient.

Patient Consent for ESRD Treatment

Patient consent for outpatient dialysis treatment or for a kidney transplant is required before the initiation of such treatment. Previous dialysis treatment in the hospital and/or surgical placement of a vascular access or peritoneal dialysis catheter is not synonymous with consent for outpatient treatment. Thus, each ESRD facility has a written consent for treatment which must be signed by the patient or his/her legal surrogate prior to treatment being performed.

Because the ESRD Conditions for Coverage (Federal Register, 1976, 1983) require that the patient be informed of his/her treatment options at the time of giving consent for a specific ESRD treatment, this consent thus actually serves as documentation that the patient has been informed

of all treatment modalities available and provides the alternatives to the impending treatment as is commonly included in all medical/surgical consent forms. Because of this requirement, all patients should know that hemodialysis, peritoneal dialysis, renal transplantation, or no treatment are options available to them. It could be presumed, therefore, that the patient's signature on this consent form not only allows for the performance of the treatment that the patient is about to undergo but also that he/she has made a conscious choice to undertake the chosen treatment.

Informed consent for the life-sustaining technologies of dialysis or transplantation thus requires that the patient be fully informed of his/her options, of the benefits and complications of each of these options for that individual, and that the patient have an opportunity to make a decision about which treatment is best for him/her. Notwithstanding medical contraindications to a treatment, the patient should then be able to receive the treatment he/she chooses in a timely manner.

Statement of the Problem

As a nephrology nurse caring for ESRD patients for more than twenty years, this researcher has observed several important problems that confront ESRD patients initiating treatment. These problems include the following:

1. Patients have had varying pre-treatment health care interventions for and education about their renal disease and the need for replacement therapy.
2. Many patients seem unaware of the availability of various treatment modalities for ESRD.

3. If patients know about different modalities, they may or may not have correct and valid information about these treatment modalities, how to access and undertake their treatment of choice, and the potential success of this treatment for them.
4. Patients appear to undertake various decision-making processes regarding treatment for ESRD ranging from making no decisions to maximal control of their circumstances.
5. The informed consent documentation which patients sign at the initiation of treatment may or may not reflect the knowledge and understanding that they have about their options for treatment as it purports to do.

While the ESRD Program assures in its regulations that a patient with chronic renal failure can receive treatment (and presumably the treatment of his/her choice), these regulations govern patient care and ensure treatment only when and following the time that the patient actually initiates treatment. Formal verification that the patient has been informed of his/her treatment options is documented after treatment has begun via the Patient Life Care Plan (Appendix B); this document provides written verification that the treatment modality which the patient is undergoing is the one he/she has chosen; this document may or may not validly indicate why other treatments were not chosen. Not infrequently in her clinical work, this researcher has discovered that the completion of this form is the first opportunity that the patient has been given to learn about alternative treatments. The information given to the patient remains dependent on who is providing the information including variables of how expert that person is, what biases are held by that person, that person's skill in explaining information clearly and

understandably, and when this information has been provided relative to the initiation of treatment. Thus, the ESRD Program regulations do not actually ensure that the patient is informed of his/her treatment options before treatment begins; the Life Care Plan signed after treatment begins may reflect only the quality of information about treatment modalities that the patient has previously received.

In summary, this nurse researcher is concerned that patients undergoing ESRD treatment may not be fully informed about their treatment options and may not be aware that they can make choices about treatment modality before any specific treatment is initiated in a manner that allows them to give fully informed consent for their ESRD treatment.

Purpose of the Study

The purpose of the study undertaken by this researcher is to document variables that may influence the potential ESRD patient's decisions about his/her treatment. In investigating this process of decision-making, the variables of sociodemographic influences on patient decision-making and how other persons such as health professionals, family, or significant others may influence patient decision-making will be documented. In addition, information about the patient's use of the health care system may identify the role that access to and the organization of the health care system play in the patient's decision-making process about ESRD treatment.

Significance of the Study

To date, no studies have been performed to determine whether patients are informed/educated about their treatment options for ESRD. In

addition, there have been no studies to determine what factors influence patients' decision-making about ESRD treatment modalities. If this study identifies that patients are not being appropriately educated about or assisted in the choice of ESRD treatment most beneficial for them, remedies can be designed to correct this problem.

The recent completion of the Congressionally mandated ESRD Program Study "Kidney Failure and the Federal Government" (Institute of Medicine, 1991) may increase the significance of the results of this research. Based on her interviews and discussion with patients who are currently undergoing ESRD treatment, Edith Oberley (1991) reported to the IOM Committee that patients stressed the importance of "getting enough information so that they could take an active role in their treatment decisions" and that they want their physicians to "provide information and reassurance so that they may take active roles in their own treatment and rehabilitation."

If the sociodemographic variables measured in this study show significant relationships to problems in decision-making or choice of treatment, further investigation should be carried out to determine whether appropriate interventions can resolve these problems and provide patients with a more satisfactory type of treatment. Treatment for ESRD can be designed to provide the patient with the highest level of quality of life, rehabilitation potential, and success in a most cost-effective manner. This study will provide initial information from actual patients to determine whether these goals are being achieved with their medical treatment.

CHAPTER II

CONCEPTUAL/THEORETICAL FRAMEWORK

Review of the Literature

To study the process that patients undertake to make decisions and choices about ESRD treatment, a number of theories and concepts have been reviewed to identify a framework which would define and guide this research. Medical, sociological, and philosophical literature were specifically reviewed in the areas of medical decision-making, patient choice of treatment, and informed consent; literature on access to care was also reviewed to attempt to discover a framework which could be applied to the patient making a decision about ESRD treatment. The nursing literature was reviewed in similar categories to identify similar research or reports about patient decision-making.

A seminal report which defines informed consent in the broadest fashion is that of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982). The relationships between access to health care, patient decision-making, and professional decision-making in assuring valid informed consent for treatment were clearly identified in these writings. This report describes how each of these aspects impact on a patient's informed consent process. Therefore, the President's Commission reports which address informed consent in health care provide the general framework for this study.

Review of Professional Decision-Making Theories

While the process of informed consent generally focuses on the role of the patient information and education, the role and influence of health care professionals cannot be ignored. The patient-physician relationship that is intrinsically created in the private practice model of U. S. health care defines the quantity and quality of education and information that the patient receives from his/her physician. Thus, the beliefs that professionals hold and the approaches that they take to decision-making about patient treatment are critically important to the patient's informed consent. It is thus important to review the theories, models, and studies that address professional decision-making.

Elstein et al.'s (1982) review of approaches to medical decision-making provides a comprehensive review of the approaches, theories, and research methodologies used to assess and evaluate the decision-making process. They defined the two general approaches to decision-making as being prescriptive or descriptive in nature. According to their definition, decision analysis as a formal device is both a prescriptive and prospective process since its use concerns what should be done and what action should be taken as a result of the decision made.

A number of writers have applied this form of decision-making (decision analysis) to medical practice. The most prolific group of writers/researchers in the medical literature are physicians who practice within the organized Division of Medical Decision Making in the Department of Medicine of the Tufts University School of Medicine/New England Medical Center and Medical Service of the Veterans Administration Medical Center in Boston, MA.

In one of their earliest reports, Pauker and Kassirer (1975) described their model of therapeutic decision-making in terms of cost-benefit analysis. They outlined a method of analysis which measured the benefit of treatment vs. no treatment based on expected values of the actions taken. The cost/benefit analysis could then be calculated mathematically based on expected value outcomes. They described this method as applicable in the face of medical uncertainty and useful in including "soft" clinical data in a decision-making process (Pauker & Kassirer, 1975). This utilitarian, expected-value approach to decision-making via a mathematical model assigns total responsibility for its implementation of patient interventions to the physician. Pauker's model does not acknowledge at all a role for the patient in the decision-making process; the patient would seem to be the passive recipient of the physician's final decision.

Kassirer (1976) defined the use of the decision tree method and its application to diagnostic medical situations; according to his analysis, the outstanding clinician is the one who has the "ability to make the rational decisions that lead to optimum therapeutic outcomes." He defined factors involved in determining the expected value of outcomes as including the probability of complications of the treatment; the gravity (utility) of each of the complications; the probability of various therapeutic outcomes; and the utility of each of the responses to therapy (Kassirer, 1976).

Kassirer's model places maximum emphasis on choice of treatments for a clinical problem, the potential complications (including morbidity and mortality), and the benefits to be obtained from the treatment chosen. Kassirer did acknowledge that the patient is involved in this process but

assigned total responsibility to the physician; he stated that "though the assessment of probabilities is exclusively the responsibility of the physician, the assessment of utilities must be done in cooperation with the patient and the family" (Kassirer, 1976). This is to be done by eliciting the patient's values so that they may be used in the decision-making process. No further application of this patient input in the formal process is defined; no branch of the decision tree as illustrated by Kassirer provides for use of patient preferences (values) in the measurement of a utilitarian outcome. If Kassirer believes that rational decision-making is a "cardinal characteristic" of the clinician and that it is his/her professional responsibility, it is unclear how patient values or preferences can be a component of his model even though he acknowledges their existence and role.

Ransohoff and Feinstein (1976) discussed Kassirer's model and its application in clinical medicine. They raised the very real issue of "who" assigns the utility values that are assigned to the possible outcomes and "who" does the assessment; they noted that the decision-maker could be a "patient, a hospital, or 'society'." Their suggestion was that clinicians who utilize the component parts of a decision-making process may be helped in "understanding, dissecting, and improving the elements of clinical judgment" (Ransohoff & Feinstein, 1976). Thus, they emphasized the benefit of the process without giving ultimate importance to the calculated outcome.

The subsequent writings of Pauker and Kassirer continued to define and refine the process of decision-making in the clinical medical setting; their 1986 article discussed the decision analysis process as applicable not only for diagnostic but also for treatment decision-making; they

indicated that the process is "particularly well suited for problems involving uncertainty: in diagnosis, test results, treatment, or prognosis" (Plante, Kassirer, Zarin, & Pauker, 1986).

In 1987, Pauker and Kassirer provided a progress report on the use of decision analysis in clinical medicine. They now indicated that "the principal purpose of decision analysis is not to provide a single optimal patient management strategy, but rather to explicate the competing issues in a problem domain" (Pauker & Kassirer, 1987). This statement reflected a real change in the application of decision analysis from that of providing an outcome for the clinician to its serving as a tool in the process of delivery of patient care. However, a second report in 1987 returned to the explicit mathematical approach to decision analysis implementing both Bayes theorem and decision trees loaded with statistical probabilities (Pauker & Kassirer, 1987).

Harold Sox's (1987) corresponding editorial to this report in the New England Journal of Medicine supported both the qualitative and quantitative aspects of decision analysis but emphasized that the skills and expertise for its use are still not present amongst clinicians. Pauker and Kassirer have consistently agreed that clinicians remain uncomfortable with and unable to carry out decision analysis in their own practice; their current comments in this regard are not dissimilar to those Pauker wrote in 1979 when he noted that physicians find decision analysis problematic because it seems to require precise and reliable data (which may be lacking to them), is more time-consuming, and minimizes reliance on intuitive judgement. Eight years later, he again noted that the time required in a formal decision analysis remains impractical for practicing physicians (Pauker & Kassirer, 1987).

Another article by Pauker (1982) on prescriptive medical decision-making focused less on a mathematical model for arriving at decisions and was more philosophical in its discussion of the process and techniques used in decision-making; he defined the process as including the traditional role of consultation ("integration of opinions") with colleagues about patient management. He defended the use of decision analysis based on its explicit nature; this requires that all assumptions be explicit in the process, including those of patient values. He actually emphasized this point by acknowledging that the patient can supply data about "his preferences about alternative outcome states" during the decision-making process (Pauker, 1982).

Pauker and Kassirer have reported this decision analysis model in these several narrative reports. While they included the schematics of a decision tree with the assigned probability scores, none of these reports provided data on the actual use of the model in clinical settings or any results of using the model. In their articles, they did use some clinical situations as examples, apparently illustrating how it has been used in their affiliated institutions to determine diagnostic and treatment courses. However, these were never complete case studies illustrating competing ideas, patient preferences, or final outcome.

This writer could find no case reports or analysis of the use of this model in actual clinical settings in any other facility or by any other physicians. The validity of this decision-making model thus remains unknown. While not specified in their reports, this model is apparently computer-based; the use of a program which includes the mathematical risk factors for each decision has a certain appeal as maximally scientific. This writer's greatest concern about its use, however, is the inability of

the authors to determine whether the patient has a role in this decision-analysis model; they frequently vacillated in their writings about the inclusion of the patient's values/preferences in their model and were also unclear how these values/preferences were included in the process when they indicated that they should be included.

Tversky and Kahneman (1981) provided a prescriptive approach to the decision-making process which is somewhat different from the strict mathematical models of Pauker and Kassirer. From their psychological perspective, they defined it as a "decision frame" to allow for inclusion and acknowledgement of the "decision-maker's conception of the acts, outcomes, and contingencies associated with a particular choice."

In their model, they recognized that the "frame" of the decision-maker includes both his/her formulation of the problem as well as his/her own personal characteristics. This method allows for a decision to be approached in more than one way; it also necessarily allows for different choices by different participants in the process. While Tversky and Kahneman did not apply their theory to medical decisions, they noted that the rational decision-maker uses the highest expected utility process but also acknowledged the phenomenon of persons making choices which are incompatible with the expected utility theory. They identified that the person's "response to loss is more extreme than the response to gains" in regard to making decisions (Tversky & Kahneman, 1981). In acknowledging this phenomenon, they inherently recognized that the person affected is involved in the decision-making process rather than being a passive recipient of someone else's decision-making for them (Tversky & Kahneman, 1981).

This effect of decision framing on the part of patients is well illustrated in the research of McNeil, Pauker, Sox, and Tversky (1982), who studied the response of "patients" with lung cancer to information presented regarding treatment options (surgery vs. radiation therapy).

These researchers framed outcome data in terms of mortality rates vs. survival rates for each lung cancer treatment. Using an experimental design, the researchers used three groups to measure the effect of framing on patient decisions; the three sample groups included 238 male patients with other chronic medical problems, 424 radiologists taking postgraduate courses at the research site (sex distribution unknown), and 491 graduate students from the Stanford Business School who had completed courses in statistics and decision theory (sex distribution unknown). The age differences of the groups included a mean age of the first group of 58 years, second group 43 years, and third group 29 years; the third group was specifically chosen to measure the effect of age and analytic training on the decision-making process. For half of the respondents (distribution unknown), the outcomes were blinded as to whether they were surgical or radiation therapy outcomes to eliminate the prior conceptions or misconceptions about these therapies that these subjects might have.

The results obtained by these researchers supported their hypothesis that patients responded more positively when treatments were identified, when outcomes were given as life expectancy rather than cumulative probability, and when probability of living rather than probability of dying was presented. This process of framing by the patient (the effects of presentation) exemplifies the role that the professional can have in influencing (or biasing) the decision-making process.

Analysis of McNeil et al.'s (1982) results indicated that all of the subjects were influenced by the nature of the data presented about therapies and the way in which it was presented. The therapies that were framed in terms of survival were chosen above those that were presented in terms of mortality by all groups. The greatest weakness of this study is that it is simulated and thus does not measure the effects of anxiety and stress that a patient experiences when actually confronted with a diagnosis and treatment alternatives. Since the results of McNeil's study in normal subjects favor the selection of therapies when they are framed in terms of survival, it can be assumed that real patients would respond even more strongly to therapies framed in survival as a positive outcome. The implications of these findings for health care professionals' interactions with patients are of major importance.

In relation to the impact that framing can have on decision-making, Tversky and Kahneman (1981) further identified a concept of "minimal account;" according to their definition of this concept, people will generally evaluate the acts or circumstances they are confronting only in terms of the direct consequences of the act. They believed that this concept most appeals to persons because it reflects direct causality between acts and outcomes, because it simplifies evaluation and the stress of thinking about problems, and because it pays more attention to desirable/undesirable changes than to a situation of no change. This mode of framing might especially appeal to the physician making therapeutic decisions because it limits the amount of information required for decision-making and appeals to the therapeutic outcome (consequences causally linked to acts) which the physician strives to achieve; maximizing desirable over undesirable changes is also a goal of the

physician during the process of therapy and is easily measured as a successful outcome in the medical process.

Descriptive approaches to decision-making have also been used in the health care setting. Elstein et al. (1982) defined descriptive studies as attempts to analyze the variables of clinical judgements and decisions in cases of differing clinical recommendations. This descriptive analysis is more useful to future situations as such analysis provides information to improve future clinical judgement.

By their very nature, descriptive studies are often evaluative and retrospective in nature. The methods of data collection are by chart review, direct observation of situations, and structured case analysis. Rather than providing a result of "truth" (best outcome), this method provides data for careful analysis and general conclusions to be drawn from the results studied. Unlike the prescriptive approach discussed previously, the descriptive approach would not be applied to the single patient in a bedside setting. Elstein et al. (1982) acknowledged that the obvious weaknesses in the descriptive approach include the possibility of erroneous self-reporting, rationalization, unwillingness to admit mistakes, or ignoring other contextual features of the decision process.

The use of artificial intelligence systems in medicine theoretically incorporates a professional expert's reasoning and clinical judgment about a specific diagnostic or treatment problem; the "production" rule incorporated in such systems "states that if certain conditions are met, a particular action or step is appropriate" (Elstein et al., 1982). Pauker and Kassirer's model for prescriptive decision-making by their computer-generated decision tree would seem to qualify as this type of artificial intelligence model.

Elstein et al. (1982) pointed out that these systems may be unnecessarily restrictive for evaluating clinical reasoning. He made a major observation about measuring information processing by clinicians when he suggested that the production rule can be measured simply by comparing the decisions (plan) for action and the action taken. Another descriptive approach to decision-making is that of social judgement theory. This model measures the relative importance of the factors (variables) used in making clinical judgments (decisions). Using written structured cases which specifically contain all of the possible variables to be measured, the researchers are able to code and weigh the judgments made by the clinicians. Thus, the identification and analysis of conflicts in clinical judgment that may exist between clinicians can be measured because of the common data base. This simulation, however, can be criticized most importantly because it may exceed the "real world" situation by providing all the information and variables to be considered in making a clinical judgment; all too often, all the data (variables) needed for the perfect clinical decision are not available.

Ethical Approaches to Clinical Decision-Making

Prescriptive decision analysis as described by Pauker and Kassirer (1987) and Sox (1987) provides the clinician with a method of making both diagnostic and treatment choices for an individual patient. Using quantitative data, this method has special appeal as a "hard" scientific approach to the professional who approaches medicine as a science; the approach diminishes the "art" (the soft, qualitative aspect) of medicine. In a society increasingly driven by computers, this technique is likely to have ever greater appeal.

Descriptive decision analysis, in contrast, provides the results to establish expert clinical judgment which can be translated into a normative base or a "gold standard" for the practitioner. While cases may differ slightly in their variables, these norms can still be applied.

Several ethical and humanistic issues arise when medical decisions are made in this fashion. Some of these problems have been identified in the decision-making and decision analysis literature; however, a more complete discussion of these issues is found in the literature on biomedical ethics and, specifically, the literature on informed consent. In this society, the decision-making that is reached by the clinician most likely leads to clinical actions/interventions. For the physician's decisions to be carried out in these medical interventions, the consent of the patient is frequently (although not universally) required. The science of decision analysis thus must be artfully applied during the interaction with the patient to obtain informed consent and achieve a therapeutic goal.

Many clinicians and philosophers have provided commentaries and theories about the decision-making role of physicians within the context of physician/patient relationships and interactions. These are areas of clinical practice historically governed by ethical principles. Thus, their discussion and analysis within an ethical framework is entirely appropriate and valid.

One of the most common ethical dilemmas that arises in situations of decision-making is that of paternalism which is the attitude and process by which an individual (i.e., the clinician) makes decisions for another (i.e., the patient). In Hill's text as recently as 1979, Pauker explicitly advocates the practice of medical paternalism when he writes

that "medical decisions are made almost exclusively by the physician. Most patients are comfortable with this because they trust their physicians to be knowledgeable and skillful" (Pauker & Pauker, 1979). He commented on the threats to this position by describing "two outside pressures;" he identified the first pressure as "an effort to contain medical costs and improve the quality of care" by payors for care thus requiring "the physician to document and justify his management plans"; the second pressure was that "patients are demanding an increased role in the decision-making process" (Pauker & Pauker, 1979).

In 1988, Harold Sox said something quite similar, although it was veiled in the more acceptable framework of "patient advocacy;" he said that "one of the physician's roles in society is to be the advocate of the patient" (Sox, Blatt, Higgins, & Marion, 1988). He believed that this role of doing the "best" for the patient must take place even in opposition to the needs of society; however, he did not define his concept of "best." The role of advocacy here is not disputed but the aspect of responsibility for what is best for the patient still sounds synonymous to paternalism.

Forrow, Wartmen, and Brock (1988) also commented on the role of ethics and informed consent in treatment decisions, by noting that "decisions should be made from the perspective of the patient" because this "approach to decision making is rooted in the doctrine of informed consent."

It is this issue of health care decisions and informed consent that the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research addressed in their report MAKING HEALTH CARE DECISIONS (President's Commission, 1982). Their studies and

report implicitly refute the paternalistic role that is advocated by some (as reviewed above) in regard to clinical decisions. In the introduction, they hypothesized that discussions and concern about a model of informed consent which reflects only medical decisions and recommendations by the practitioner may be "a token of larger changes in the relationship between patients and health care professionals, especially physicians" or "because of a particular cultural attachment to independence and autonomy" or because of the "growing importance of biomedicine in people's lives" or "skepticism over 'expertise' in many spheres" (President's Commission, 1982).

Physician/Patient Relationship

The hypotheses about the changing nature of informed consent identified by the President's Commission do address the role of the physician/patient relationship. In discussions of the relationship and the communication process between the patient and physician, the art of medicine again dominates over its science. Physicians can undoubtedly recognize that the communication of the results of a decision analysis, application of the knowledge gained from descriptive approaches to decision-making, and application of the theory of decision framing are often elements in the interaction between patient and physician that result in consent and achievement of the anticipated clinical outcome.

The cornerstone of this entire process of informed consent is the assumption that the two involved parties (physician and patient) have a relationship with each other. Society seems to presume that such relationships exist based simply on an interaction between the two parties; if the patient sees the physician (even if only once or

occasionally), a relationship is apparently initiated and thus exists. Therefore, only in the most emergent situations would such a relationship be ignored by health care professionals. If it is assumed that this patient/physician relationship exists, then it is the quality of the relationship which dictates the manner in which decision-making will occur, informed consent will be obtained, and a satisfactory clinical outcome will be achieved.

Perhaps the first description of the physician/patient relationship in modern medicine is that provided by Talcott Parsons (1951). According to his analysis, the increasing scientific knowledge and tools available to the physician presumably made the patient less able to fully understand the medical treatment required. The "good" patient undergoing these increasingly sophisticated and technical treatments and interventions was defined as the one who cooperated fully without need for education or full understanding about what was being done for him/her. The negative aspect of Parsons' theory, however, elicited another definition--the patient who was not "good" was labeled as being deviant. The stigma of deviation was serious and became an effective means of defining the patient role and thus also the physician role. The successful physician/patient relationship would be based on good patient performance with the assumption that the physician was also always beneficent.

One of the earliest writers about the role of physicians and patient is Eliot Friedson, a sociologist who has studied the structure and function of U. S. health care (Friedson, 1970). In writing about the physician-patient relationship, he defined it at being "inherently problematic" with the physician and patient coming together for a common result but with different perspectives of both the problem and the method

of managing it. He ascribed these differences to the expertise and knowledge of the physician in caring for a patient who is apparently completely incapable of comprehending his/her illness and the rationale for its treatment. He thus perceived the patient role as relying on "faith and confidence" in the physician's work (Friedson, 1970). To assure patient cooperation, Friedson further identified how physicians can help patients "obey" them; he recommended that the physician use "persuasion." By these statements, Friedson seems to support Parsons' (1947) assignment of technical competence and authority to the physician and the use of the formal structure of the health care system as the best method to elicit cooperative patient behavior (Friedson, 1970).

A significant aspect of Friedson's writing about the physician-patient relationship is his attention to the problems of cultural and educational differences (presumably only on the part of the patient); he recognized that differences in the perception of health and illness, the roles of patient and healer, and the etiquette of consultation can make medical care difficult or actually impossible (Friedson, 1970). In this multicultural American society and health care delivery system, it is important to apply these same concerns to the cultural heritage of the physician and the impact that it might have on the physician/patient relationship.

Friedson (1970) viewed the educational level of patients as being less problematic but spoke against health education of the patient as solving problems that may exist in their physician relationship; his argument against the benefits of health education is very weak as he used only the example of the health care professional (physician) as "worst" patient. He did not suggest that other aspects of the physician/patient relationship might overcome this problem.

Another method of influence in the physician/patient relationship which Friedson (1970) viewed as valid is that of physician prestige as identified by the socioeconomic status of the physician and perhaps even his institutional stature and protection. Presumably, the patient is of lower socioeconomic status (and education) and would thus view the physician as more powerful. However, Friedson (1970) does not discuss the type of influence that the physician can utilize with the patient of equal or higher socioeconomic status and/or education. Does institutional stature and protection still wield influence over these patients in the form of "the medical mystique?" The alternative to this possibility is that the physician/patient relationship is discernably different when these influences cannot be applied.

Friedson's work has been an important contribution to the definition and analysis of the role of the physician in his/her relationship with the patient. It is unclear whether his theories are still relevant in the physician/patient relationship twenty years later or whether changes in the health care system have actually occurred to affect or change the physician/patient relationship as Pauker has more recently hypothesized.

Kass (1980b) analyzed the physician/patient relationship through the perspective of the "physician's service." He noted that "the superiority of trusting in the prudence or discernment of the practitioner in specific cases presupposes that the practitioner understand in general what his practice is and what it is for;" this stance required that the physician view his/her practice as humanistic and altruistic (Kass, 1980b). He alleged, however, that multiple nonmedical factors influence (often negatively) the beneficial role of the doctor-patient relationship.

Kass further raised questions about whether a physician serves the patient's needs or his desires and wishes. He questioned whether the physician serves the patient's good or his rights and whether the physician is reduced to a servant of the patient in the modern physician-patient relationship. Kass suggested that the "language of service" is not appropriate for describing the physician/patient relationship; he defined the relationship as one of co-worker and helper or a leader and patient teacher in regaining and/or maintaining the patient's health (Kass, 1980a).

It would appear from this definition of the physician role and responsibility in the relationship with a patient that neither physician paternalism nor patient autonomy can dominate. Kass apparently refuted both the most traditional role assigned to physicians and the most modern role assigned to patients.

Thomasma (1983) more explicitly rejected both medical paternalism and patient autonomy as appropriate in the physician-patient relationship. After providing arguments against both paternalism and autonomy, he proposed the "conscience model." This dynamic relationship allows for consensus of decisions between patient and physician to be reached but assigns special responsibility to the physician to recognize patient vulnerability and the implicit power that the physician derives from the vulnerability of the ill patient. In addition, he charged physicians to respect the moral ambiguity that occurs in medicine and in the physician-patient relationship (Thomasma, 1983).

Interestingly, Thomasma's "conscience model" shares great similarity with a much older model of the doctor-patient relationship as described by Szasz and Hollender in 1955. In their model, identified as "Guidance-

Cooperation," they acknowledged the power and knowledge that the physician has and the possible paternalistic, exploitative nature of the relationship (as Thomasma has recognized); this model, however, assigned the patient a different role from that seen by Thomasma; they described the patient as totally powerless in this relationship, thus creating a paternalistic doctor-patient relationship. However, the model that Szasz and Hollender advocated as being best, the "Model of Mutual Participation," requires that patient and physician assume approximately equal power, are mutually interdependent, and that both achieve some satisfaction in the activity of the relationship. Without the use of modern jargon, Szasz and Hollender have described a role of patient autonomy in a relationship of cooperation between the physician and patient which is negotiated based on mutually agreed upon goals of therapy.

Finally, the farsightedness of Szasz and Hollender in regard to decision-making as part of the physician/patient relationship seems to have been described when they noted that this model emphasized therapeutic interaction between patient and physician to determine what the health of the patient should be; in this situation, the physician does not necessarily know what is "best" for the patient (Szasz & Hollender, 1955).

Szasz and Hollender defined their model of mutual participation as having a more highly developed psychological and sociological nature and suggested that it is inappropriate for "children or for those persons who are mentally deficient, very poorly educated, or profoundly immature" while noting that it becomes more appropriate to employ in the circumstance of greater "intellectual, educational, and general experiential similarity between physician and patient" (Szasz & Hollender,

1955). This aspect of the model would resolve the issues raised by Friedson's theories of physician influence over patients of lower educational and/or socioeconomic status.

In 1979, Eisenberg described similar sociological aspects of the physician-patient relationship (based on sociological factors) and their impact on clinician decision-making. In his review article, Eisenberg defined the physician-patient relationship as a social interaction between patient and physician that is influenced both by the sociologic variables of patient class, income, race, and general personal characteristics as well as by the physician's own personality and his relationship with his profession (Eisenberg, 1979).

Following his review of the literature, Eisenberg concluded that these factors play a role in decision-making and in the clinician-patient relationship; he also noted that other professionals (e.g., nurses) can have the same factors operating in and influencing their relationships with patients. He noted the paucity of literature which reviews how physicians do behave vs. how they should in regard to patient relationships and clinical decision-making (Eisenberg, 1979). This lack of study and documentation of physician behavior continues.

Multiple other articles report on the success of the physician-patient relationship as measured by patient satisfaction, patient participation, understanding of patient beliefs, and obtaining informed consent (Lidz & Meisel, 1983; Marquis, Davis, & Ware, 1983; Martin, 1983; Meisel & Roth, 1981, Speedling & Rose, 1985; Starfield et al., 1981). Similarly, the Report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982) framed its study and report on the ethical and legal implications of

informed consent "within the broader context of relations and communications between patients and health care professionals." While verifying many of the findings in more specific articles and reports, they acknowledged that their recommendations about the informed consent process remain visionary and should be used as the "goal toward which all participants in health care decision-making can strive."

The Physician-Patient Relationship and Patient Decision-Making

Philosophical support for the involvement of the patient in medical decision-making is found in Brett's (1981) editorial about the ethical aspects of decision analysis, in Cassell's (1982) article on patient suffering and the goals of medicine, Arnold, Povar, and Howell's (1987) article describing the nature of the humane physician, Kass'(1980a) article on the ethics of the physician/patient relationship, Martin's (1983) outline for exploring patient beliefs to enhance the physician/patient relationship, Speedling and Rose's (1985) description of how to progress from patient satisfaction to patient participation, and Thomasma's (1983) model of physician conscience in the patient/physician relationship. All of these commentaries described an active role for patients in decision-making and participation in their care. These writers also assigned the responsibility for providing or assuring patient participation to the physician, specifically making suggestions re: his/her relationship or interaction with the patient.

Notwithstanding the formal theories and models of decision-making about health care, there are few empirical studies which measure "how" this process really occurs. Several research studies to be reviewed here have verified that such relationships and empowerment of the patient are

possible. Other studies verify the difficulties that patients confront in regard to decision-making and how these difficulties are often due to their understanding or lack of understanding of the problem they are confronting.

Starfield et al. (1981) analyzed follow-up visits of patients receiving care in an HMO outpatient setting. In this study, both patients and physicians were asked to identify which problems required followup, the perceived seriousness of the problems, and the patient's concern about the problems. The results of this study indicated that the problems identified by both the patient and physician were seen to be of greatest concern to both parties. However, the severity of the problem was not a shared concern. In addition, the agreement of both patient and physician on which problems required followup care improved the outcome of that problem.

A primary question raised by this study is whether verification and validation of the patient's beliefs or concerns enhances decision-making. The authors do not describe the treatments for these patients' problems and whether the patient or practitioner were in agreement about the treatment; more importantly, they do not describe what process was used in reaching that agreement. Is agreement about problems synonymous with agreement about treatment of those problems?

Strull, Lo, and Charles (1984) measured by questionnaire the preferences of patients in participating in the decision-making process and their physicians' estimations of the patients' desires for greater participation. According to their results, patients actually wish to receive more information about their medical condition and problem but often do not wish to participate in decision-making about treatment;

physicians underestimated the amount of information that patients desired while overestimating their desire for participation in decision-making.

Lo, McLeod, and Saika (1986) carried out a similar study of discussion and decisions about life-sustaining treatment. They discovered that most patients who participated in their study had considered and made decisions about life-sustaining treatments but few had discussed these decisions with their physicians. While a majority (68%) of their subjects wanted to discuss this matter with their physician, only 6% had done so; 53% of the patients wanted physicians to initiate such a discussion. This research supports the admonitions of those writers who suggest that the physician take a leadership role in encouraging the participation and decision-making role of patients.

Using an experimental design, Greenfield, Kaplan, and Ware (1985) actively involved a group of patients with ulcer disease in their care by having them review their charts and by coaching them to ask questions and participate in medical decisions; a second group of patients with ulcer disease were provided only with standard educational sessions about their disease. The results of the study indicated that the patients who were actively coached were less limited by their disease, preferred their active role, and were as satisfied with their care as the control group.

Two basic problems are identified in this study design which may have influenced these findings. Firstly, the second group should not be considered as a true control group since another intervention had been used which may not be available to all ulcer patients. Secondly, the intervention for the experimental group was provided by individuals other than the patient's physician. Therefore, this study does not prove that the physician's role can be developed to enhance patient participation and

decision-making about their treatment. Greenfield's research could be used to support this role for expert nurses who would educate and support the patient in this process.

Casselith, Zupkin, Sutton-Smith, and March (1980) surveyed 256 cancer patients to elicit information about how much these patients wish to be informed about and participate in their care. While they determined that these patients did wish to participate in their care, they also determined that the patient's age and state of hope about his/her illness were important variables in the degree of information and participation desired; younger and more hopeful patients wished to be more involved in their medical care. By reporting the differences created by these two variables, these researchers remind us that all patients are not alike; practitioners must elicit the patient's preferences in regard to desire for information and participation in the decision-making process for their care. These research studies do not use a formal model or theory of decision-making in their design; they are apparently based on general beliefs or descriptions of physician/patient interactions and relationships.

Using a theory of decision-framing, McNeil, Pauker, Sox, and Tversky (1975) carried out a simulated study to measure responses and decision-making in regard to the diagnosis of lung cancer using the theory of decision-framing. This research (reviewed more completely earlier in this report) does provide a valuable example of utilizing a theoretical framework in analyzing patient decision-making.

Without specifying this theoretical approach, Leonard, Chase, and Childs (1972) may well have been measuring decision-framing theory when they interviewed parents of children with genetic diseases or conditions.

Their study identified that only half of the parents (patients) who had received genetic counseling had a good grasp of the information they had received; the researchers attributed the difficulties experienced by the rest of the participants to the "context" in which the counseling was provided. While they did not define "context" specifically, they did indicate that it included the "variable skills" of the physicians and the consumer's (patient's) knowledge of biology. Their research revealed that the "risks" of genetic diseases as it might impact on further childbearing or the childbearing of their children was often denied by these persons; the risk statistics given to the parents were poorly understood or misinterpreted. However, the "burden" created by the care for the child with genetic illness was much better understood and was more relevant than risk in regard to decisions about subsequent childbearing.

The authors enumerated several reasons for the difficulties experienced by these parents including the physician's personal qualities, ability to communicate, and the satisfaction that the patient felt with the physician. The researchers reverted to dependence on the patient/physician relationship in describing their findings even though the theory of framing may also dictate the burden/risk interpretation by the subject (patient).

Using a quasi-experimental design, Roter (1977) measured patients' participation in their care. This design required the random assignment of female patients from a family and community health service to experimental and placebo groups. The 100 patients in the experimental group received a 10-minute intervention with a health educator prior to their visits with the health care provider; the patients were coached in the process of asking questions regarding their illness/treatment. The

control group received a 10-minute session reviewing information about other emergency and specialized services available to them. Tape recordings made during the physician visit, a 15-minute interview-questionnaire administered to the subjects immediately after their physician visits, and analysis of appointment-keeping records for a period of four months before and after the study process were used for data analysis. Roter's study of patient participation in care following specific educational sessions found that the patients who received more information about their illness had patient-provider interactions which were "characterized by negative affect, anxiety, and anger while the placebo group's patient-provider interaction was characterized as mutually sympathetic" (Roter, 1977).

What effect did this negative or positive interaction have on patient decision-making? Actually, the experimental group (the educated patients) were less satisfied with their care but, even so, were more compliant in appointment-keeping than the placebo group. The author was unable to fully explain these findings. Just as noted with Greenfield's study, this study does not indicate an alteration in the physician/patient relationship which is based on the physician's interactions with the patient. Using a surrogate to coach, educate, or support the patient creates changes in the patient's behavior which changes the physician/patient relationship but does not support any of the philosophical commentary about the physician's professional responsibility or skills in doing this.

Finally, two studies specific to discontinuation of dialysis therapy (withdrawal of life support) measured the process of making this decision that takes place between the patient and physician (Neu & Kjellstrand,

1986; Silva & Kjellstrand, 1988). In both of these studies, the authors described the process of decision-making by physician and patient or family in the face of patient incompetence; using chart review case analysis, they analyzed the roles of physicians and patients or families to determine who served as the initial decision-maker and the changes that occurred over time in regard to decision-making in this situation.

While these studies do not measure initial treatment decision-making, they serve to illustrate that descriptive studies can be accomplished to measure the decision-making process. The major bias in these studies may be the strong relationship between patient and family and the physician. By studying discontinuation of treatment, it presumes and measures the strength of that relationship. In addition, no information was provided to determine "how" these decisions were made, who initiated the discussion, and what information was included in these discussions.

These quasi-experimental and descriptive studies of physician/patient interaction and the decision-making process by patients do provide some information about how these processes may work or be perceived by patients.

Nursing Literature on Professional Decision-Making

Florence Nightingale (1860) recognized the problems and process of decision-making for/by patients at a most basic and most important level. In NOTES ON NURSING, she writes that "Conciseness and decision are, above all things, necessary with the sick . . . ." "Irresolution is what all patients most dread . . . . A change of mind in others . . . always injures the patient more than the being called upon to make up his mind."

Can this statement be interpreted to mean that Florence Nightingale recognized that both physicians and patients have roles in the decision-making process about the patient's treatment? While she goes on to describe nursing activities (tasks) to illustrate these concepts, this writer suggests that these concepts apply to modern aspects of nursing science and practice in regard to patient decision-making about care and treatment.

The Code for Nurses (American Nurses' Association, 1976) described the ethical expectations and requirements of the nursing profession. In its first statement, this code requires nurses to provide "services with respect for human dignity and the uniqueness of the client." The accompanying interpretive statement describes the autonomy of the patient in being involved in his/her health care planning and treatment including receiving information, knowing the effects of treatment and care, and having the right to "accept, refuse, or terminate treatment."

The nursing obligation is to know, protect, and support these ethical and legal rights of patients. Thus, the nurse has an active role in assuring and protecting the right of patients to have full and complete information and education about his/her illness and its treatment, including the benefits, side-effects, and complications of the treatment; the nurse's obligation is to verify that the patient has received full information either by educating the patient and/or reviewing what the patient understands to assure that they have been appropriately educated and informed. Based on this interpretation of the ANA Code of Ethics, nurses should have very active roles in the patient decision-making and informed consent process.

Friedson's analysis of the role of nursing, however, refuted such responsibility and obligation by nurses (Friedson, 1970). He disagreed that nursing is a profession which is capable of performing independently but rather that the nurse is subordinate to both the physician and hospital. If that is true, the nurse cannot have any responsibility in patient decision-making and informed consent.

While it is not within the context of this study to determine which of these views is correct, these conflicting definitions of the nurse's role are relevant to this study of patient decision-making. Friedson's views are undoubtedly still held by some physicians and supported by institutional policies thus creating conflicts for individual nurses in caring for their patients.

While there is a vast amount of literature about informed consent in health care, the nursing literature in this specific area is sparse. Davis studied the process of nurses' ethical decision-making in both clinical and research situations of informed consent (Davis, 1989). This study used both vignettes and semistructured interviews with 27 registered nurses working in a large medical center and a city hospital. Her research found that both institutional and personal philosophical influences determined the nurses' responses. Because of the structure of these two settings, positive mechanisms were in place to protect the informed consent process including peer review, informal support systems, ethics rounds, ethics committees, IRBs for research, and bioethics conferences.

Questions unanswered in the reports of this study include a description of the 27 nurses in regard to their nursing experience, level of education, formal coursework in bioethics, and other demographic

aspects (age, ethnicity, religion, etc.) to determine if these are variables influencing the nurses' perceptions. A similarly relevant issue is how strong each of the two variables (institutional and personal philosophies) is. An additional question raised by this research is whether the safety nets of open and direct communication and the skilled assistance that Davis identified as being important to nurses are available for the problematic cases in different situations/settings. Of special interest is whether the nurses' responses would be different in a different hospital setting; community or private hospitals may have very different structural supports which could impact on their perceptions.

Finally, the selection by nurses of specific work settings may reflect the agreement of their personal philosophies with those of the institution. Are the nurses who work in different settings also different in regard to their perception of ethical decision-making in informed consent; do they view their roles differently or are other variables about them different? As Davis noted, more studies are on this subject are needed to understand the nurses' role in the process of informed consent.

Nurse-Patient Relationship and Decision-Making

The nursing literature is relatively sparse in regard to the nursing role and patient decision-making. Nursing has defined its role as providing patient information and education without formally relating these functions to patient decision-making.

One report in the nursing literature does discuss the role of nursing in the decision-making process for patients. Pomorski (1983) discussed the decision-making of the aged for surgical procedures within the context of the informed consent process; she defined the role of the

nurse in regard to the decision-making process as providing the patient with information, education, and support, clarifying information given by the physician, and intervening between the physician and patient as needed. She described the nurse as being an advocate for the patient and in being empathic in that role. While she identified the aged as the recipients of these nursing functions, it seems only appropriate that all patients should receive such nursing care. These are, of course, the responsibilities and actions that are outlined in the first statement in the ANA Code for Nurses (ANA, 1976).

The sites of nursing practice also contribute to minimizing this function. Private physicians' offices are generally not staffed with expert nurses whose role includes education and consultation regarding the patient's decision-making about his/her illness and its treatment. In the acute hospital setting, the patient has apparently already made major decisions regarding his/her illness and treatment and has been hospitalized to carry out these decisions. Nurses, therefore, are infrequently in a position to be involved with patients as they access the health care system and have to confront their illness. Clinics and home health care settings may allow for nurses to educate patients and counsel them regarding treatment decision-making.

Limitations to these nursing functions may be created by staffing patterns (heavy case loads or high nurse/patient ratios) or minimal emphasis on these functions in the nurse's job description. In addition, nurses may not feel that they have the knowledge and skills to perform these functions in specialized areas of patient care. Nursing referrals to expert clinicians would be appropriate in this circumstance but probably seldom occur.

There are areas of practice where nurses are more frequently directly involved in assuring patient decision-making and informed consent. Nurses who recruit patients as subjects for research protocols actively participate in their decision-making process. Nurses who are involved in organ donation similarly are intimately involved in a family's decision-making process about a patient. In these roles, however, nurses function with a clear bias of recruitment or of convincing the individual to make a certain decision which benefits the nurse's and the system's purpose. In addition, the nurse has a vested interest in the patients' decisions that are made. The patient's decision reflects the success or failure of the nurse in his/her work. Finally, the nurse also usually represents the interests of another, most often a physician, in assisting with patient decision-making or obtaining consent. Thus, these types of processes are unlikely to provide complete information or answers to questions about the role of nurses in patient decision-making.

Professional Decision-Making and the ESRD Program

The history of treatment of ESRD provides interesting and unique examples of medical decision-making. When the technology of dialysis became available for human (clinical) use and when renal transplantation was clinically possible (as measured by function of a transplanted kidney for months/years of time), the constraints to implementation included availability of equipment (dialysis machines and artificial kidneys), trained personnel and adequate geographic distribution of those personnel, appropriate physical facilities, coverage and reimbursement by existing health insurance plans for this costly treatment, and a relative shortage of healthy, suitably matched kidneys from cadavers or family members for transplantation.

These constraints were translated into the process of "allocation of scarce resources" which meant that not all patients with kidney failure could or would receive dialysis and/or transplantation. Thus, decisions had to be made by someone to determine who would receive this life-saving treatment; historically, this decision would rest with the physician as the primary provider of care who could determine what would be best for the patient.

This decision-making activity (between life and death because of resource availability), however, was apparently not acceptable to physicians as their singular responsibility. The Northwest Kidney Center, which was the first outpatient chronic hemodialysis facility in the U.S., seemed to solve the dilemma of decision-making about patient selection for treatment by organizing committees of physicians to make these decisions. These committees were subsequently reorganized to include lay persons from the community to assist in making these decisions (Alexander, 1962; Fox & Swazey, 1974). Scribner (1972) described this solution as a "fairly reasonable and simple" one to this decision-making problem.

No one raised the question of whether physicians were abrogating their professional responsibilities as decision-makers for their patients; this approach was apparently more acceptable because of the nature of this "social and medical experiment" in treatment (Scribner, 1972).

Alexander (1962) brought this unique process to the attention of the American public via her article in LIFE Magazine in which she described the "radically unorthodox step of involving laymen in making life-or-death decisions about a candidate's acceptability for this medical procedure." This article provided the American public with a dramatic description of this approach to a health care decision-making process.

Katz and Proctor (1969) did study this new method of decision-making about candidates for dialysis and transplantation; they collected data from 93 of the 120 existing dialysis centers in 1967 and found similar patterns of decision-making being implemented. They specifically documented the "nonuniform and uncertain nature of this decision-making" process and found that medically suitable patients were evaluated and selected for treatment by "patient selection decision-makers."

Hampers and Shupak (1967) documented this type of decision-making process by both medical and nonmedical personnel in their text LONG TERM HEMODIALYSIS. Their written verification of this process provided additional validation of the use of this process for the professional community.

This decision-making process by physicians and lay committee vote did not remain an acceptable method for members of the health care community, the lay committee members, or for potential patients, their families, and friends. Political pressures and lobbying efforts gathered both public support and Congressional attention; the efforts of individuals and newly formed advocacy organizations resulted in the passage of P. L. 92-603 (Federal Register, 1976) which established Medicare/Medicaid funding for renal disease treatment. Passage of this legislation thus eliminated the need for these methods of decision-making for patient eligibility.

Recently, Raisa Deber has investigated the current role and methods of medical decision-making in the ESRD Program (Deber, Barnsley, & Blidner, 1982). Using a descriptive approach to decision-making and drawing on the work of cognitive psychology for studying the way physicians make decisions, Deber created a model for medical decision-

making that focuses on the medical encounter process and what occurs in that process, especially in the process of treatment decisions. She distinguished her model in regard to treatment rather than to diagnosis. This is an important discrimination; the models previously reviewed here have tended to emphasize the diagnostic portion of the medical encounter/decision making. This is particularly true of the work of Pauker and Kassirer in their model of decision analysis. In focusing on the decisions about treatment which follow the diagnostic phase, Deber emphasized the discreteness of the treatment decision in the physician-patient interaction.

Deber (1982) also attempted to emphasize that treatment outcome is different from the evaluation of outcome which is the final step in other decision-making models. Deber's model identified three factors involved in the treatment decision process; she described these as follows: (1) disease, treatment, and patient specific factors; (2) institution specific factors, and (3) practitioner specific factors. She believed that these three factors are used by or impact on physicians as they make treatment decisions. Deber used this framework to measure the decision-making process of physicians in regard to the treatment of ESRD patients. Applying this framework to a group of nephrology clinicians, Deber used a simulated case analysis to measure their decision-making in choice of treatment for ESRD patients.

She reported the design and results of her studies in a 1986 report (Deber, 1986). Using 18 vignettes which included various patient-specific factors in a multifactorial fashion, her first study determined the most important patient-specific characteristics and treatment choices. These 18 vignettes were mailed to 232 practitioners in Canada and Michigan who

treated ESRD patients; the respondents were asked to indicate their first treatment choice and all other acceptable choices (from a list of 10 possibilities) for these "patients." From that initial survey, she developed 6 case studies for a second survey of practitioners.

Because she requested that all individuals in a facility be allowed to participate in this study, she received 764 completed questionnaires from various staff members (94 nephrologists, 36 other physicians, 483 nurses, 146 other nonphysicians, and 5 who did not indicate their position). Her response rate was enviably high; 79% of the eligible units in Canada and 61% of the eligible units in Michigan responded. Her reported results include the total percentage of first choice of treatment for the 6 case studies; she also reported the percentage of responses indicating other acceptable treatments.

Because Deber also collected data about the respondents themselves and the institutions in which they worked, she was able to measure the relationship between treatment choice, practitioner-specific characteristics and institution-level characteristics; she found that institution-level characteristics were more important than practitioner-specific characteristics. Logistic regressions on the first treatment choice for these cases found few significant differences for experience, delta risk, delta effectiveness, delta desirability, physician/non-physician classification, unit mean, risk attitude, self choice, and location (Canada vs. Michigan) as source of information.

In a previous report (Deber, Blidner, Carr, & Barnsley, 1985), Deber analyzed the core and matching variables which her research had identified as the most important variables to physician decision-making. Using 6 core case studies (vignettes), she also developed two "matching" cases for

each core case, one of which added one piece of critical information and the other changed only superficial information. These case studies thus allowed for interrater reliability to be established in regard to the core variables tested. These 18 case studies were sent to a randomly selected group of physicians, nurses, social workers, and patient care technicians in Canada and to 22 members of a committee of renal experts who had helped in questionnaire development. In Michigan, the ESRD Network distributed the questionnaires to 212 practitioners. She discovered that age is the most important patient characteristic variable in the respondent's treatment decision-making process; the other core factors of sex, employment status, and availability of potential treatment partner (for home dialysis) reflected in the case studies had no significant effect on treatment choice by the respondents. The matching case effect was not significant for most of the situations; the respondents continued to agree on first choice and other acceptable choices of treatment.

Deber's work in regard to patient choice has provided the ESRD community with a great deal of information about how they make treatment decisions for patients. The careful design of these studies and the development of the vignettes using expert guidance and pretesting strengthen her results. Her vignettes were quite realistic in describing ESRD patients; the greatest weakness is that she did not include ethnicity as a factor or variable in these vignettes. The amount of agreement on treatment modalities in all of these studies by the various respondents is not surprising but may be disturbing; it may reflect that the community has reached a "status quo" state and no longer is using any real individual or innovative approaches to treatment choice. It is also surprising and disturbing that there was major agreement between

respondents in Canada and Michigan; these two health care systems have long expressed differences in their health care agendas especially in regard to cost-effective ESRD treatment regimens. From these research results, it is unclear whether practitioners in the state of Michigan reflect the norm of practice in the U. S. or whether their practice is more like their close Canadian neighbors. This research raises unanswered questions about geographic influences on the process of professional decision-making.

The hypothetical nature of this research (a paper exercise using simulated cases) may also allow the physician or other health care professionals to give the "best" response--one that they believe would be the most acceptable to others, of the highest human value, and in closest agreement with their colleagues. There is the understanding on the part of the practitioner that these are not real cases and thus the decision-making can reflect what he/she "should" do rather than what he/she might "really" do. Do these responses reflect what happens in real case situations when decisions about interventions are made on an emergent basis or when all the information about the patient is not known? A study to correlate these theoretical responses and actual behavior of these health care professionals would be useful to measure these variables.

From the brief descriptions of these case vignettes in Deber's reports, they seem to be generally good cases of middle class people with whom the professional can most easily identify. The more difficult cases of the chronically unemployed, the homeless, the mentally disturbed, the drug addict, or the very aged were not well reflected in these case studies; the variables of ethnicity and cultural differences were also not included. The results are thus biased by the limited construction of the

case vignettes. Deber argued that using real cases/actual decisions might pose ethical problems and may not be able to distinguish between referral effect and practitioner preferences. By controlling for these variables, however, Deber's work did not reflect the real world and the range of decision-making that professionals must confront.

Deber did acknowledge the role of other professionals in the decision-making process; she included the responses of both nurses and social workers to her questionnaires. In the study of patient characteristics, however, she did not comment on variation or agreement of responses between types of health care professionals. In the study of practitioner-specific characteristics, the results of comparison of physicians and other health care professionals was not significant; the meaning of this is unclear but may suggest that practitioners have all been similarly oriented in an "institutional" fashion (as Davis found in her study of nurses).

Finally, Deber made no mention of patient preferences in her research; because it was beyond her decision-making model and research design, she seemed to agree with her colleagues who believe that the patient has no significant role in the decision-making process about their treatment. Deber's research and findings, however, have provided a major attempt to examine the professional decision-making process in ESRD treatment.

Mattern et al. (1989) surveyed nephrologists in three different geographic regions to determine their preferences in the use of 6 different ESRD treatment modalities. While noting that these regions were socioeconomically different, the report did not contain any documentation of these differences. These researchers measured practice patterns of

physicians in these three geographic areas by reviewing the treatment modalities used by patients in regions of North Carolina, Southern California, and Australia/New Zealand. Their findings indicated very different patterns of treatment utilization in each of these areas. In addition, they measured physician preferences for treatment using a questionnaire of treatment pair analysis under three different clinical conditions: (1) for patients in general; (2) for patients with diabetes mellitus, and (3) for patients over age 60.

These researchers also collected demographic data about the nephrologist completing the questionnaire. Preferences expressed by the nephrologists were compared to actual utilization patterns of treatments in each of these regions and between the regions of study although their preferences were not compared to the actual practice patterns of the participating nephrologist. The results showed similar patterns of suggested practice amongst the participating nephrologists with variations from that being practiced in the actual regions. These regions also remained quite distinct from each other in regard to actual practice even though the nephrologists more closely agreed on preferences of treatment. This study at least partially answers the question of whether health care professionals "practice" what they preach; this research suggests that nephrologists may not agree in their expressed treatment decisions and actual treatment may not reflect their expressed treatment decisions.

The researchers do give several general explanations for these similarities and differences in the nephrologist's theory and practice. Again, no attention is paid to the role of patient preferences in regard to treatment decision-making in this study. No recommendations are included to correct for these actual practice differences and the

nephrologists' theoretical preferences that were found in this study.

Hamburger et al. (1990) developed a "dialysis decision guide" using the compiled experience of six dialysis centers. This report focused on the use of peritoneal dialysis as a treatment modality and provided a decision matrix which included categories of medical, demographic, and psychosocial factors. While no data were cited to support the individual criteria in each of these categories, they were apparently based on the clinical experience of the practitioners participating in the report. This matrix allows for individual patient medical decision-making based on physiologic findings, demographic issues relevant to delivery of care, and psychosocial issues which include patient values and preferences. No reports of use of this matrix are included in the report. Unlike the other studies and reports, this decision-making matrix does include patient preferences and values in its process of decision-making. This report may serve as a reminder for practitioners that their decision-making about the patient's ESRD treatment modality should include assessment of these variables; while the authors recommended use of these variables to determine peritoneal dialysis as a preferred treatment modality, they are really general enough to be applied to decision-making about all ESRD treatment modalities.

Finally, the ESRD Program has frequently been subject to discussions of another type of decision-making model, that of cost-benefit analysis. Unlike Pauker's decision tree model which is applied to single cases, the discussions of cost-benefit analysis in the ESRD Program have been at a macro-allocation level. Roberts, Maxwell, and Gross (1980) presented their computer simulation model of the ESRD Program which included both survival time and direct costs of various ESRD therapies. As is well

known in the ESRD community, their results verified that transplantation is the most cost-effective therapy while center-based hemodialysis remained the most expensive. The authors, therefore, encouraged practitioners to shift treatment modalities away from center-based hemodialysis. However, no other cost-benefit variables were included in this study nor were personal costs to the individual patient considered in this study so it is unclear how these factors would affect their results and recommendations. Do ESRD physicians include costliness or cost-effectiveness as a variable in treatment decision-making? Deber (1982) did not include this variable in her model, Hamburger et al. (1990) made no specific mention of it, nor could any other reports be found regarding this variable. Can and should this variable be measured in any analysis of decision-making about ESRD treatment?

Summary of Professional Decision-Making Theories and Research

Clinical decision-making remains an elusive part of professional practice for the physician and has a small, if any, role in current nursing practice. The literature reviewed in this paper illustrate that the various disciplines have attempted to define how decision-making occurs or how it should occur in health care. Physicians have essentially taken two theoretical approaches to decision-making. Pauker and associates espouse a prescriptive type of framework which lends itself easily to computerization and mathematical analysis.

Using this method, a decision tree is formed which results in the "best choice" being made in a rational manner. The outcome created by the decision process is also predicted in a highly accurate fashion. The deficiency in this model is that its designers and advocates seem to be

unclear about whether the patient has a role in the decision-making process and how to integrate that role if it exists. While Pauker and colleagues describe the use of this framework in their reports, it has not achieved widespread use, perhaps because of its rigorous nature.

Psychologists have developed the decision-framing theory which can be applied to medical decision-making. As Tversky and Kahneman (1981) described it, this theory identifies that decisions made by patients are "framed" or influenced by the manner and context in which information is given to the patient. This theory has been used in an excellent research study by McNeil, Pauker, Sox, and Tversky (1975) validating the framing theory. In addition, this theory values and emphasizes the role of the patient in clinical decision-making.

Social judgement theory is a descriptive model using written structured cases which are employed to measure how clinicians make decisions. These simulated cases can be used to measure clinicians' collective agreement/disagreement about their decision-making process and clinical application. Both Deber et al.'s (1985) and Mattern et al.'s (1989) research on ESRD treatment decisions used this theoretical framework to measure consensus among nephrology practitioners in regard to treatment decisions.

In addition to these theoretical approaches, several physician philosophers have written commentaries about the role of physicians in the decision-making process. These commentaries generally emphasize the physician/patient relationship as it enhances or hinders decision-making about treatment. These writings describe how physicians should interact with their patients but fail to identify how physicians learn to establish or maintain these relationships with patients.

Nurses have generally played minor roles in patient decision-making, primarily providing support and education to the patient in relation to their decision process; nurses apparently do not relate these functions to the patient's decision-making process. The nursing literature describes and supports these two functions as the nurse's role in patient decision-making, but it has not emphasized this role in actual patient decision-making through research or clinical reports.

The ESRD Program, its patients, and practitioners should have a special interest in the theory and process of clinical decision-making. This program provides treatment for chronic renal failure for more than 100,000 individuals; these patients have the choice of three specific treatment modalities for their disease yet there is little information about the way in which they and their physicians make these decisions about treatment. Similarly, little is known about the way in which nurses may be or are involved in these decisions. This program could provide a wealth of knowledge about clinical decision- making from the perspective of each group of its participants.

Patient Decision-Making Theory

What theories and frameworks of medical decision-making can be applied to this process for these two groups of patients--those who are acutely ill and those who become progressively ill? How does the physician-patient relationship that is existent or suddenly initiated influence the patient's decision-making process?

As described by Elstein et al. (1982), the prescriptive and descriptive approaches to the analysis of medical decision-making allow for the measurement of patient involvement and participation; he

specifically noted that including patients and families in the decision-making process enhances the clarity of clinical reasoning and clinical outcome.

How do patients evaluate the outcomes of treatment based on the probabilities presented by the clinician? Slovic, Fischoff, and Lichenstein (1980) identified the difficulty that the patient may have by suggesting that the value structures of most individuals in regard to new situations such as diagnosis, illness, and treatment options are not sufficiently internally coherent and consistent to allow for decision-making. Thus, an important part of the decision-making process is for the individual to actually identify and shape his/her values and preferences in regard to illness, treatment, and continuing life.

Wadsworth (1974) suggested that "patients often have quite specific ideas as to the nature and cause of their complaints, and the type of treatment required" and that physicians must discover what these beliefs are. If the dialogue between patient and health professional explores these areas of the patient's understanding of his/her illness, the value structures that Slovic et al. (1980) described can begin to be identified and measured. Wadsworth (1974) requires the physician to be the leader in this regard--to "break into the patient's pattern of thought as to what is wrong, why it is wrong and what needs to be done about it, in order to be sure of his patient's cooperation in getting the correct diagnosis, and in choosing the appropriate form of treatment."

In direct contrast to the traditional sick role (exemption from responsibility about illness and complete cooperation and trust in the physician and the medical regimen), that had been defined by Talcott Parsons (1951), society has come to believe that patients have both the

right and responsibility to be actively involved in the clinical decision-making process. This belief has been legitimized via regulations and legislation concerning the informed consent of the patient (Faden & Beauchamp, 1986).

In 1956, Szasz and Hollender proposed a totally different role for the patient than that espoused by Parsons. They suggested that the best model was that of "mutual participation" in which the patient was able to be an equal participant in his care because he is empowered to do so with the necessary information about his illness and its treatment (Szasz & Hollender, 1956).

While Brody (1981) expressed some strong reservations regarding the amount of patient participation in making medical decisions and establishing treatment goals, he proposed four steps that could be taken by the health care system to ensure participation by the patient; they are as follows: (1) "establishment of a conducive atmosphere"; (2) "ascertain the patient's goals and expectations"; (3) "educating the patient about the nature of the problem, discussing the pros and cons of alternative evaluations and treatment approaches, and, when warranted, presenting and explaining the physician's recommendations"; and (4) "eliciting the patients' informed suggestions and preferences and negotiating any disagreements between physician and patient."

The initial period of illness, when the patient first accesses the health care system, is often the period of greatest decision-making about the patient's diagnosis, condition, and subsequent treatment; yet, it may also be the time when the patient is least prepared to make decisions because of the amount or type of information he/she may or may not have about the illness and because there may be a new relationship with the

physician who is providing care, thus making communication or discussion more difficult. In actual practice, therefore, Brody's methods provide a challenge in ensuring appropriate patient decision-making.

Pauker and associates have written a number of opinions about the role of the patient in the decision-making process (Kassirer, 1976; Pauker & Kassirer, 1975; Pauker & Kassirer, 1987; Pauker & Pauker, 1979). As noted previously, their prescriptive model of decision analysis seems to provide no real role for patient involvement. In particular, their model could be interpreted as assuming that once the patient enters the health care system, the physician can and should proceed with diagnosis and management following the appropriate decision tree with the full cooperation of the patient (e.g., as Parsons' good patient). They would assume that the patient's access and entry into the health care system ensures his/her full cooperation with the physician's treatment plan (which is based on a decision analysis framework). One can also hypothesize that when that cooperation on the part of the patient is not forthcoming, the patient's access to the system could be restricted or denied.

An analysis of the selection process for dialysis and transplantation in the early years of treatment before the ESRD Program existed might show a decision tree structure that looks much like Pauker's prescriptive theory of decision-making. In that process, the patient had no direct role; all that he/she could contribute was the desire to accept the decision of the committee and to follow its recommendations. The selected patients also implicitly, if not explicitly, obviously agreed to be "good patients."

ESRD Patient Decision-Making

As previously described, patients who develop ESRD are confronted by two paths of development and diagnosis of this disease state. For an untold number of patients, the scenario is that of an acute illness requiring hospitalization and immediate renal replacement therapy as the patient is both acutely and chronically uremic; these patients may not have been receiving ongoing medical care or that care might not have addressed the problem of chronic renal disease, at least not in a manner that the patient could comprehend.

No actual data is available from the ESRD Program regarding the frequency of such an acute presentation or the number of persons who are undiagnosed or medically untreated prior to needing ESRD replacement therapy. For this population, it is clear that decision-making about continued treatment will begin at the time of diagnosis and immediate need for treatment. For some of these patients, this circumstance of acute illness and emergent decision-making may occur because it is created by access or gatekeeping behaviors of the health care system (refer to section on access).

For people who are aware of their diminishing renal function, the decision-making process about definitive treatment when they reach ESRD can be carried out very differently. These patients have the time and, hopefully, the opportunity to obtain information about ESRD treatment and to decide which treatment modality may be best for them.

Several reports in the professional nephrology literature and by nephrology patients suggest that these patients receiving ESRD treatment have special relationships with their primary physician and with other staff in regard to their decision-making activities and processes. Lidz

and Meisel (1982), from their research for the President's Commission report, found that nephrology patients who were hospitalized were very actively involved in making decisions about their care, particularly in relation to repeated vascular access surgical procedures.

Similarly, in her book THE COURAGE TO SURVIVE, O'Brien (1983) emphasized the positive role that ESRD patients exercise in their long-term care. On the other hand, Plough (1986) concluded from his observational research in a single dialysis facility that paternalism reigns in the physician-patient relationship and that patients seem to be actively suppressed by staff in regard to decision-making.

Other single reports of decision-making appear in the literature written by both professionals and patients (Coleman & Davidson, 1981; Levy, 1974; Oberley & Oberley, 1979); many of these patient reports are accounts of their own decision-making from which other patients might learn. In addition, several of these reports are arguments for or against the various types of therapy available. Classically, these arguments in nephrology have centered on the choice between dialysis and transplantation (Anderson & Bartkus, 1978; Levy, 1974; O'Rourke, 1981). These reports and analyses have obviously been written retrospectively; the observations were made about and by patients who were already in the system and had possibly been empowered by it.

Perhaps the most poignant report of the conflicts for ESRD patients in making decisions about treatment alternatives was written by Calland (1972) who was a young, practicing physician at the time of initiation of ESRD treatment. He labelled these conflicts as "iatrogenic problems" in the treatment of end-stage renal disease and noted that the patient often suffered in this process. He focused on the conflicts and competition

between the treatments of dialysis and transplantation which he felt that the physicians generated and which adversely affected ESRD patients.

Oberley's (1991) recent study through group interviews of patients' concerns about ESRD treatment was previously reviewed in relation to their preferences about decision-making and active involvement in their care (Oberley, 1991). These ESRD patient interviews were conducted in several geographic areas throughout the U. S. Recommendations for patient participation in these study groups were made by their health care providers. This selection may have created some bias in the participant group; random sampling would have decreased this possible selection bias.

One other study has been published which reports aspects of patient decision-making about treatment modalities. McCauley, Johnson, & Copley (1989) studied a selected group of ESRD patients who were receiving treatment at the Walter Reed Army Medical Center to determine their knowledge of probabilistic outcomes of both dialysis and transplantation. The questionnaire that they used in asking patients about the relative success of ESRD treatments found that this group of patients were quite accurate in their percentage estimate of various treatment outcomes; they were actually more accurate than the group of physicians questioned.

These researchers suggest that patient accuracy in understanding the outcomes of alternative treatments was at least due, at least in part, to the close relationship between the patients and their physicians in this single setting although no data or other information was provided to support this hypothesis. Not only is this a single setting, but it is likely to be a highly organized one by its nature of being a military facility; thus, these findings should not be generalized to other settings such as private practice and free-standing dialysis programs.

While the researchers acknowledged the personal experiences that these patients have obtained from their own observations while receiving dialysis and transplantation, they seemed surprised at the reality reflected by these experiences and that these patients could process information accurately and without need for denial. Most importantly, this study measured the estimations of experienced ESRD patients who have already had to make important decisions about their own type of treatment and have also discussed with and observed in their fellow patients the results of various treatment modalities.

This study did not report on whether patients found their relationships with health professionals or with fellow patients more significant in understanding the results of treatment. The researchers' failure to measure or control for the variable of patient/patient relationships weakens the results of their findings, especially their hypothesis that this patient awareness is due to a close patient/physician relationship. In addition, these results are probably irrelevant in regard to the patient who is making decisions and giving informed consent to initiate treatment.

There are two other specific issues that continue to confound discussions about the ESRD patient's decision-making and informed consent process. These two issues are (1) the patient's denial of his/her illness (ESRD) and (2) the uremic state (retention of waste products in the blood) affecting or interfering with the patient's ability to comprehend information or to think clearly enough to make a "rational" decision.

The neurologic effects of uremia are directly attributed to the increased concentration of end products of metabolism (particularly urea nitrogen) in the central nervous system; this increased concentration can

result in an encephalopathy as measured by slurred speech, gait imbalance, asterixis, action tremor, multifocal myoclonus, seizures, and clouding of the sensorium (Raskin & Fishman, 1976). It is this clouding of the sensorium which supposedly interferes with the ability of the patient to think clearly; alterations of alertness and awareness of the environment are early indications of the development of this encephalopathy. As the uremic state worsens, patients become preoccupied and may exhibit impaired concentration although these periods are episodic with periods of good mental performance; perceptual errors and defective recent memory and mild confusion also may appear (Jennekens & Jennekens-Schinkel, 1983; Raskin & Fishman, 1976).

These signs of uremic encephalopathy cannot be correlated with specific levels of uremic toxins in the blood (particularly blood urea nitrogen); these signs may be more or less intense relative to the rate of development of renal failure. Thus, the patient who has been developing chronic renal disease/failure over an extended period of time (i.e., months or years) will exhibit fewer of these symptoms than the patient who develops acute (and usually reversible) renal failure (Fishman & Raskin, 1976; Jennekens & Jennekens-Schinkel, 1983). Jennekens and Jennekens-Schinkel (1983) also note that these signs and symptoms may remain subclinical with gradual decrease of renal function, maintenance of fluid and electrolyte balance, good nutritional management, and blood pressure control.

The patient with chronic renal disease who has been receiving appropriate medical management should therefore have minimal signs and symptoms of uremic encephalopathy. The practitioner thus also has the opportunity to provide the appropriate information, education, and support

to the patient about his/her impending renal failure and need for ESRD treatment prior to the development of a clouded sensorium or at those times when the patient is most lucid and clear. Thus, the patient's uremic state should not preclude his/her decision-making and consent about future treatment following appropriate education and discussion about available treatment options. Only those patients who have not been receiving ongoing medical management might have an altered sensorium from their uremic state which would make their decision-making or informed consent about treatment potentially more difficult or less valid at the time they present to the health care system.

Although this researcher could find no current reports documenting the neurologic status of patients approaching ESRD, it has been her clinical observation over the past several years that most patients initiating dialysis have not had significant alterations in sensoria due to uremia. It is also not uncommon for patients to continue to work and take care of all their personal affairs up until and even throughout the period of initiating treatment. In addition, physicians do not usually suggest that patients are incapable of performing work or other normal activities due to uremic encephalopathy; patients do not have to discontinue driving, for example, due to alterations in sensorium or being able to make judgements nor are they deemed incompetent to sign legal documents, including giving consent for ESRD treatment. While some patients may take short medical leaves from their jobs when they initiate treatment, some patients do not even feel the necessity of doing that.

Assuming that these observations about the neurological aspects of chronic renal failure are correct, it is impossible to believe that uremic neurological changes would prevent most chronic renal failure patients

from participating in a rational process of decision-making processes about treatment.

The second issue often raised in discussions about patient decision-making is that of denial. For purposes of this report, the definition of denial as a psychological mechanism used by patients to prevent their having to deal with the reality of their medical condition is most appropriate.

Anna Freud (1946) described denial as a process "which interferes with accuracy in the perception of the outer world by excluding the unpleasurable." Such a process is common to persons facing or dealing with illness; the psychiatric and medical literature is replete with reports and studies of denial during illness, especially life-threatening illness. For example, Hackett, Cassem, and Wishnie (1968) described denial as a mechanism used by patients in the intensive care unit to cope with their fears about their medical condition and possible death. Kubler-Ross (1975) identified denial as one of the stages in the process of dying; her work made all of these stages, including denial, commonly understood and popularized by both health professionals and the public.

Marshall and Walmsley (1978) discussed denial as part of the grief reaction using Kubler-Ross' model; they described the response to the loss of a body function as being similar to that of impending death. In addition, they described patients as being able to deny the nature and severity of their illness even though they have been "carefully and explicitly" informed until they can cope with the full implications of their illness.

Cummings (1970) described denial as "patient behavior that is contrary to consensual expectation . . . after complete explanation of the

medical factors as they are known." His definition of denial could be construed to explain deviant or irrational behavior as it is judged by others. The use of his definition might also allow patients to be labelled or stigmatized as deviant or irrational, a judgement which could adversely impact on their care.

The hemodialysis patients treated in the 1960s were a totally new and different population in regard to their physical and psychologic status--they were persons with a terminal illness being kept alive and functional outside of a hospital on a machine. These patients were expected to live "normal lives" and to be patients only during their treatment times or when experiencing other acute medical problems/complications. Their reactions and responses to this existence were initially well-studied by psychiatrists, psychologists, and sociologists; one of the areas of study was the use of denial by this patient population.

One of the earliest studies was reported by Short and Wilson in 1969; using the MMPI and supplementary scales for this testing, they identified that increasing denial occurs in the hemodialysis patient population. Their conclusion was that these patients deny their current situation and that their families may also develop a pattern of denial. Most importantly, these researchers suggested that denial in this population may need to be maintained rather then resolved to allow these patients to cope with their life situation. Other than the administration of this testing, this report did not describe the actual research design that led to these conclusions.

Foster, Cohn, and McKegney (1973) carried out a study of hemodialysis patients to identify specific psychosocial and physiological

high-risk factors to predict patient outcome. Using multiple psychological tests to assess psychometric variables for 21 Veterans Administration patients, they discovered that these patients demonstrated denial; they also found that those patients who exhibited significant denial (e.g., not identifying themselves as hemodialysis patients) survived significantly longer than the other patients. While the sample was small and most likely biased to male participation because of the VA setting, it was especially significant for that time period. The design was particularly comprehensive in its use of appropriate measures of both physiologic and psychologic variables.

Goldstein (1972) also studied denial in the chronic hemodialysis patient population; without describing the population he studied in more detail, he reported that he had to discontinue the patient interviews that would provide subjective data from the patient about his/her life and the effects of chronic renal failure on it because several patients refused to participate in such interviews; he ascribed this unwillingness to their state of denial. He also found himself reluctant to perform the interviews and felt this was an expression of his own denial about this stressful illness and his plan to measure it. Thus, his dissertation reported not only on this observation of patient denial but also on staff denial as he observed his own and three other situations involving clinical staff. His work supports the conclusion that denial is useful for patients in coping with their situation but that it may be an occupational hazard for staff including interference with professional recognition of problems and their resolution.

Finally, Fortner-Frazier (1981), from her position as an expert ESRD clinical social worker, indicated that denial is the primary defense mechanism used by people on dialysis to cope with their situation.

Caution about extrapolation of the results of these various psychologic studies to the ESRD population of today is appropriate. These studies were performed at a historic time when complications of renal failure and treatment were more dramatic and life-threatening; when all of the patients knew that they were a chosen few to receive this new treatment; and when medical technology, particularly in the form of machinery, was held in awe rather than being accepted as a standard component of health care. It is totally unclear what effect these unique circumstances had on the patient's emotional state. As ESRD patients of today do not have the burden of these special circumstances, their emotional and psychological responses may be very different. No recent studies could be found which replicated or refuted these findings in ESRD patients currently receiving treatment.

Health care practitioners seem to accept that the mechanism of denial is used by many human beings in stressful circumstances without significant adverse impact on their lives. In addition, practitioners have come to believe that denial is useful in many circumstances of acute or chronic illness allowing the patient to maintain some normalcy and longevity in their lives (as Short and McKegney found in their research studies).

The question that has remained unanswered in research studies on denial is whether this defense mechanism totally prevents the patient from being able to make decisions about his/her treatment modality and to give an informed consent for a treatment to begin. When critics use the phenomenon of denial as a reason for disallowing or minimizing the possibility of patient decision-making, they are suggesting that denial is so global as to totally block the patient's ability to comprehend

information. This researcher could find no studies which have studied and proved that the psychological mechanism of denial during the period preceding dialysis treatment, or in other illness states, impaired or blocked the patient's comprehension of information, thinking rationally about one's medical status, or making rational decisions about one's treatment.

The reports cited above are narratives which either describe specific cases or measure denial in the hemodialysis population utilizing psychologic testing methods. Given that the patients studied were undergoing dialysis treatment, their denial must have been selective to certain aspects of their renal disease. The patient who would totally deny his/her renal disease and need for treatment would either not present him/herself for initial treatment or return for continued dialysis treatment.

In addition, patients' denial regarding their illness and future need for ESRD treatment would likely be expressed by their discontinuation of medical care (being "lost to followup") and/or in not following prescribed medical regimens of medications and diet restrictions. Thus, these patients would not be able to or be interested in participating in early education about treatment or making decisions about that treatment.

Patients are often labelled by professional staff as being "in denial" when they initiate ESRD treatment. As a necessary mechanism to cope with the stress of this overwhelming event, it has been shown that denial serves a useful function for these patients. Perhaps this need for and use of denial by patients could be tempered by prior information, preparation, and decision-making about treatment thus decreasing the stress of the event.

Based on her clinical observations and experiences, this researcher also suggests that the assignment of the conditions of "uremic encephalopathy" and/or "denial" to a patient may be a convenience on the part of staff to relieve them of additional tasks and involvement in informing and providing psychological support to the patient before he/she begins ESRD treatment. Having to inform a patient of the need for life-long ESRD treatment (especially chronic hemodialysis) is having to give tremendous "bad news;" health care practitioners may wish to minimize this task of giving bad news by allowing the patient to maintain his/her denial or by assuming that the patient will not comprehend the information appropriately due to their uremic condition.

In addition, these states of denial and uremic encephalopathy have been used by health care providers to explain why patients have not remembered all they have been told. This may be a very weak argument in the face of accepted knowledge and understanding of how persons retain new information, the effect of communication difficulties or barriers that may be present between staff and patient, vagueness in explanation and information due to concerns about predicting the future, and routine use of medical jargon with minimal explanation in "plain" English. Both the conditions of uremic encephalopathy and denial need updated study to determine whether and how they influence patient decision-making about ESRD treatment.

Access to Health Care

For a person to become a patient, he/she must seek health care from some source. In the Western culture and specifically in the U. S., these sources are myriad. This paper will limit its discussion to the

traditional and organized sources of medical care used by the majority of people in the U. S.--private physicians, hospitals, and clinics.

Access to health care in the U. S. has been characterized by major ethical and policy issues, particularly within the past 30 years, because the U. S. government does not provide a national program of health care. The plurality of the system can make it difficult for the individual patient to easily access the system.

Aday and Anderson (1981) developed a framework for the study of access to the health care system: the five areas of study include (1) health policy--financing organization; (2) potential access--structural indicators; (3) potential access--process indicators; (4) realized access--objective indicators; and (5) realized access--subjective indicators. It is within this framework that access to health care for the patient with renal disease will be discussed and analyzed.

(1) Health Policy-Financing Organization: For patients with renal disease but not yet requiring replacement therapy with dialysis or transplantation, there is no single policy or financing organization which oversees or pays for their medical care. The policies and financing for the care of these patients emanate from the same pluralistic systems available to any patient seeking and receiving health care. Third party insurance, the Medicare Program, Medicaid programs, and indigent health care systems as well as direct patient payment reimburse in a variety of ways for these patients' medical expenses.

In contrast, once the patient has been certified as having ESRD, almost all of these patients (93%, according to the USRDS 1990 Data Report) enter the Medicare system for reimbursement of their treatment under the guidelines established by P. L. 92-603 and P. L. 95-292 (Federal

Register, October, 1976; Federal Register, 1983). This policy and reimbursement program for ESRD care is administered by the Health Care Financing Administration branch of the U. S. Department of Health and Human Services. Even for the patients who do not qualify for Medicare coverage, other insurance programs reimburse for care; these remaining 7% of patients may be Department of Veterans Administration or CHAMPUS beneficiaries or may be enrolled in state Medicaid or medically indigent programs for reimbursement of their health care; a small number of patients may rely only on private health insurance for continued coverage of ESRD treatment. It is even more rare for a patient to personally pay for his/her total ESRD care, but it does occasionally occur. Thus, it is nearly impossible that any patient who is a legal U. S. resident or citizen will be denied ESRD treatment for the financial reason of being unable to pay.

The transition to being an ESRD patient can actually provide a person with improved access to care due to their Medicare eligibility. However, an increasing area of concern regarding policy/financing for ESRD care are the limitations created by preferred provider agreements or other private payor's coverage restrictions affecting patient access to specific types or settings for the delivery of ESRD care, e.g., preferred provider agreements with a specific renal transplantation or dialysis facility which may not provide the patient's preferred treatment modality or which may create other personal hardships such as travel arrangements to the treatment facility, undesirable appointment schedules, or change of physician.

(2) Potential Access-Structural Indicators: This component of the framework addresses the following characteristic of the health delivery

system: availability by volume and distribution and organization by entry and structure. To define patient access by these structural indicators requires the definition of the methods of access to the health care delivery system available to patients.

People seeking health care will either choose to see a physician on an outpatient basis (in an office or outpatient clinic) or, if they judge themselves to be severely ill, will seek emergency care at a freestanding or hospital facility. Patients with chronic renal failure may choose either of these access routes depending on their perceived severity of illness.

The availability of services by volume and distribution is determined by a number of variables, including the size and location of the community in which the patient lives (small, large, urban, suburban, rural), previous contact with a physician (does the patient already have a physician), and type of health care coverage (private, health maintenance, preferred provider, Medicaid, or none) possessed by the patient. Based on his/her symptoms, the patient may not choose to see a nephrologist simply because he/she does not know the cause of his/her medical problems. Will treatment by a family physician or internist be adequate for the patient in this case? Is a nephrologist available in the patient's community?

For the patient who seeks care in the public setting (hospital emergency room or clinic), care is usually provided by generalists and/or staff in training; specialists are usually only available for consultation. However, these facilities are often organized into specialty practices/clinics which may provide the patient with ongoing specific nephrologic management following his/her first contact; referral

to private physicians may also be initiated by hospital-based emergency services. For the person who does not have a private physician, access to care may be dependent on the availability of physicians in the community to accept new patients.

For the patient known to a private physician, access to both outpatient and inpatient care is usually more easily obtained; however, the greatest variables in this situation may be the ongoing availability of the physician on a regular or emergency basis or waiting periods necessary for obtaining an office appointment.

Patient admission to a hospital facility for care is only accessed in emergency situations or via specific justification and arrangements provided by the physician to the health insurer. Thus, the greater control to access to inpatient services may be by the health insurer rather than by the physician.

(3) Potential Access-Process Indicators: This category assesses the characteristics of the population at risk by assessing predisposing and enabling factors which are both mutable and immutable and also by assessing both perceived and evaluated need. The patient at risk for developing ESRD may be easily identified based on the existence of diseases that predispose the patient to that outcome; the leading diseases in these categories are hypertension and diabetes mellitus (USRDS, 1990). Hypertension can be classified as a mutable process as it can treated in such a way as to delay or prevent the complication of renal failure (Brenner & Rector, 1976; Friedman, 1978). Diabetes Mellitus exemplifies an immutable process (Brenner & Rector, 1976; Friedman, 1978). Since these two diseases are also the leading causes of ESRD (USRDS, 1990), their management illustrates how the health care system can identify

persons at risk and provide the necessary access to medical management to prevent or delay ESRD.

Because of the high incidence of hypertension in the black population (both young and old) and its increasing incidence in white males (USRDS, 1990), these groups are at high risk of developing ESRD. For these patients at risk, enabling processes such as a continuing relationship with a physician, a socioeconomic status which can provide for continued access to and payment for medical care, and a social support system which gives continued health care a priority and positive value will enhance their access to the health care system and the treatment available to them.

The factors of perceived and evaluated need for health care reflect both the socioeconomic status and personal value systems of the patient. Is the possibility of developing ESRD because of hypertension a primary reality in the patient's life? Can he/she buy the appropriate medications without having to forego other vital expenditures such as food, shelter, clothing, etc.? What role does denial of disease play in the patient's life? How does the patient view his/ her health status? Does he or she attribute it to age or to other existing illnesses? These questions reflect very relevant issues in this specific category of access to health care.

Diabetes Mellitus can be analyzed as an immutable illness in this framework. Diabetes Types I and II are now the leading cause of ESRD in the United States accounting for almost one-third of all new patients beginning treatment in 1988 (USRDS, 1990). Patients with diabetes who are at risk of developing ESRD as a complication are usually known to the health care system and already have access to care or potential care as

needed. Their risk for development of ESRD can be anticipated and identified through routine blood and urine studies (Brenner & Rector, 1976). Enabling factors may delay the onset of ESRD; appropriate medical care can protect diabetic patients from further insults or medical events that would further compromise renal function and hasten the onset of ESRD (Brenner & Rector, 1976).

(4) Realized Access-Subjective Indicators: This component of the framework assesses patient satisfaction through the criteria of convenience, availability, financing, provider characteristics, and quality of care. For patients with chronic renal failure receiving care in multiple settings (outpatient private or public settings), the measurement of their satisfaction is usually indirect and rarely quantified. One indirect measure of satisfaction may be reflected by determining whether or not the patient continues to receive care in that setting; while professionals may measure this as patient compliance and disregard their responsibility in providing care that meets the patient's perceived needs of quality and convenience, it is these latter characteristics that may be nonverbally expressed by the patient when he/she does not return to the physician or clinic for treatment. What importance do these subjective indicators have for the patient with chronic renal disease who will develop ESRD? How do they influence the patient's current treatment? What importance do these indicators have for the patient as he/she enters the ESRD Program?

(5) Realized Access-Objective Indicators: This component measures the actual utilization of health services based on type, site, purpose, and time interval. For patients with chronic renal disease who have a private physician, the utilization of office visits for continued

assessment continues. For the patient without a practitioner but who identifies a private physician, a similar course of utilization of services can occur. For the patient who continues to use emergency services for primary care, there will be greater variability in the type, purpose, and time interval of these visits although the patient may well control care by using the same emergency room or clinic for each of the visits. Even if an initial referral and contact has been made, patients may or may not continue to see a nephrologist if they continue to see their primary physician. In addition, they may not maintain appointment schedules if they feel well (are asymptomatic) especially if they do not understand the nature of their illness.

These five aspects of access to health care determine the amount and type of care that a patient receives or that he/she can "buy;" many would argue that the amount and type of care equates with the "quality" of care although this is subject to debate. These access to care issues influence and determine the patient's decision-making process about both acute and ongoing health care and treatment. Thus, it is necessary to look at the role that access to care plays in the process of patient decision-making.

A variable in the issue of health care access relevant to this research is the one of gatekeeping which determines where, when, and from whom the patient is able to receive care, particularly specialized care. Within Aday and Anderson's framework, gatekeeping could be classified within the category of health policy--financing organization, as a potential access--structural indicator, or as realized access-objective indicator of access to the health care system. The patient's health care insurer may serve as a primary gatekeeper to obtaining either basic or specialized care, e.g., disallowing payment for care or treatment, not

providing coverage for outpatient care, or denying care due to pre-existing illness or prior condition.

In the area of potential access--structural indicator, the ability to obtain a timely appointment for medical care can serve as a gatekeeping activity which may restrict or delay access to care. Gatekeeping activities which delay care might also actually result in a patient's worsened condition leading to more urgent and expensive care.

The category of realized access--objective indicators is also an area where gatekeeping can be employed; for the patient who has access to a primary physician or system, access to specialized care generally remains dependent on physician referral to the specialist. Others in the health care system can also serve as gatekeepers to information, education, and specialized care; for example, nurses may or may not provide appropriate information and education. Diers and Molde (1983) specifically identified nurses as being the new gatekeepers in health care in their expanded role as case managers in primary care settings. Finally, other professionals such as social workers or dietitians may or may not be able to see the patient in consultation about specific aspects which may be helpful to the patient's care particularly if these referral services generate additional health care costs.

The professional who recognizes gatekeeping as a positive responsibility can assure patient access to timely and appropriate care. However, the organization of the U. S. health care system more frequently lends itself to gatekeeping activities that limit or restrict access or allow for sequestration of patients for financial reasons.

Patients with a chronic illness such as renal disease or a primary disease which has renal disease/failure as a complication are especially

vulnerable to issues of access to health care. In addition, changes in access that may be created by alterations in their health care coverage, e. g., changes in private health insurance plans, changes in preferred provider contracts, or changes/restrictions in eligibility for coverage may create an added burden or barrier for these patients.

Several studies of access relevant to ESRD treatment have been reported even though they do not always indicate a framework of access. Kjellstrand and Logan (1987) noted the phenomenon of gatekeeping at the level of the ESRD patient's primary care before the patient is referred to the nephrology specialist. Even though they reported no data concerning the frequency of this occurrence, they have attempted to document the racial, sexual, and age inequities in the chronic dialysis population; they attribute these, at least in part, to the gatekeeping process.

In this report, Kjellstrand and Logan (1987) employed complex mathematical formulae to determine what they called discrimination indices of minimum and maximum fractions treated by using HCFA data of patients receiving ESRD treatment as compared to mortality data obtained from the U. S. Vital Statistics Report. For the year 1979, they concluded that there was discrimination based on age and sex, that is, against the old (over 65), the young (under 15), and women. Their mathematical calculations showed that race as a variable of analysis revealed discrimination against whites rather than blacks in the ESRD program.

Notwithstanding the use of their unique formula for analysis, the age of this data (collected in 1979 and not reported until 1987) weakens the importance of their findings; changes made in the ESRD program may make their findings only interesting history. Replication of this study, however, using more current data is essential to determine the relevance

of the findings. These apparent barriers to ESRD treatment suggest that access was restricted at that time. Does this situation still exist? If so, what are the current and actual barriers to access?

The timing of patient referral for ESRD treatment is also an issue of gatekeeping. Campbell, Ewigman, Hosokawa, and Van Stone (1989) found that primary physicians seemed to have some difficulty in defining the appropriate process for referral of patients with chronic renal disease. Their study of referral of renal failure patients to nephrologists was carried out in the state of Missouri. With data collected from referrals of ESRD patients during the early 1980's, these researchers analyzed referral patterns for cost of initiation of ESRD treatment and patient survival after that treatment was initiated.

In addition, they analyzed the characteristics of physicians referring patients for ESRD treatment. While this study apparently was not intended to measure the phenomenon of gatekeeping, they did measure referral patterns from generalists to specialists at varying times in the course of their patients' illness. They found that referral patterns (early, late, and intermediate in the course of the patient's renal failure) did not change between the years of 1982 and 1987.

Their analysis of physician characteristics found that 90.7% of the physicians interviewed felt that they had received no special training in the patient referral process although neither the "special training" nor the exact referral process was explicitly defined in this report. In addition, the physicians who participated in the study identified 9 common themes to explain their referral patterns.

This analysis documented the greater economic cost in the initiation of treatment for urgently referred patients and a greater one-year

mortality rate for these patients; these findings were apparently unexplained by any other factor. In addition, this report specifically noted that these patients lacked knowledge of their disease and the treatments available and thus had to make emergent decisions about treatment modality when they were quite ill. Their report, however, did not indicate that even the sickest patients were unable to make decisions about treatment thus suggesting that they did not believe that the uremic state of these sickest patients interfered with appropriate decision-making.

It is unclear whether this study identified implicit or explicit gatekeeping behavior by the referring physicians. It does seem clear that the existing referral patterns affected patient outcomes. However, these researchers failed to make suggestions regarding methods for correction of this apparent referral problem.

This pattern of referral may also reflect another aspect of access to specialty care which could not be found in other reports in the literature; during the course of this researcher's data collection, several nephrologists suggested that the motivating factor for not referring patients to them until treatment was required was for financial reasons; the primary physician feared losing the income from the patient's frequent office visits.

The second gatekeeper to access to ESRD treatment remains the patient's health insurance coverage or lack thereof. The variables of ethnicity and socioeconomic status are often intimately linked to lack of coverage and are reviewed in the following section. According to these studies, the patient without insurance coverage or with minimal coverage, such as Medicaid recipients or the medically indigent, seeks medical care

more frequently in crisis situations or when he/she has symptoms of illness.

Thus, the patient with chronic renal failure who has been asymptomatic until its near terminal (uremic) stages has likely not been informed of treatment options within an ongoing medical system/ relationship. Rescue treatment will be initiated when the patient presents to the acute care facility. Not infrequently, the patient will awaken to find him/herself attached to a hemodialysis machine. While treatment has not been denied, the decision about undergoing treatment or about choosing what type of treatment to undergo has not been made by the patient either acutely or perhaps even for the long term. A life-saving treatment that has been initiated is difficult to discontinue or to trade for one that is totally unknown; the immediate security of treatment is likely to become very important to the individual.

The gatekeeper to information about ESRD care and access to that care is generally the patient's primary physician--a general practitioner, internist, or nephrologist. For the patient who has been receiving no medical care, the acute care institution and its various staff become the gatekeeper to information about and access to ESRD treatment. If the primary physician chooses not to refer the patient for this specialized care and the placement of an access for dialysis, treatment is summarily denied. If the patient is informed that treatment is available, the construction of this information by the physician or perhaps other hospital staff can result in a situation of decision framing (Tversky & Kahneman, 1981; McNeil, 1982). Is the information about ESRD treatment presented in a positive, negative, or neutral fashion? What knowledge or personal history does the patient bring to his/her own situation which will influence or frame the process of decision-making?

Another issue regarding access to ESRD treatment is that of actual choice of treatment modality. There are no reports about the choices that patients make and the relation of those choices to their ethnicity, culture, age, lifestyle, and professional bias or pressure.

Kjellstrand (1988) has analyzed the modality of renal transplantation for age, sex, and racial inequality. Using both regional and national data available from the ESRD Program, his chi square analysis identified several significant findings; white men received more renal transplants than women and black patients. In addition, transplant rates were highest for persons aged 11 to 36. In the two different time periods of study reported, these findings remained significant.

Kjellstrand's discussion provided no explanation of these findings but suggested that they were due to bias rather than coincidence. While Kjellstrand did not do so, these findings could be interpreted within a framework of access to treatment. The patient's access to renal transplantation as a treatment modality usually relies on referral by a health care professional. Do Kjellstrand's findings reflect specific referral patterns, i.e., primarily young persons and white males for renal transplantation in preference to females, older persons, or minorities? While Kjellstrand explains these findings as bias either in referral to or selection for transplantation, they may also be interpreted as restrictions on access to treatment.

Sociodemographic Variables and Patient Decision-Making

With the passage of PL 92-603 (Federal Register, 1976), essentially all persons with the medical diagnosis of ESRD were able to receive treatments previously provided only for the most economically and socially

advantaged. Equity and civil rights in health care seemed to become a reality in at least this one disease/treatment area. Following the passage of this legislation, dialysis units and transplant programs began to see a dramatic change in the population of patients receiving treatment. Rather than selecting patients based on their social worth and medical suitability, (Alexander, 1962; Fox & Swazey, 1974), patients now eligible for dialysis included children, the elderly, patients with other serious and/or near terminal illnesses, and the economically disadvantaged. Lifestyle and social criteria no longer prevented patients from receiving these life-saving treatments.

With major changes in the sociodemographic identity of the ESRD population because of equalized access, it would seem that these sociodemographic differences might have different impacts on patients' perception of illness and their decision-making about treatment. The question of what impact the patient's ethnicity, culture, and socioeconomic status have on the decisions that these patients make or that the health care system and professionals allow them to make remains unanswered.

The social epidemiology of renal disease as it might be defined by the model of Syme and Berkman (1981) has not been studied so there is little information about the social variables that might influence the causes of renal failure. For example, is the higher incidence of diabetes and renal failure in native American genetically related to ethnicity or to social variables? Ivie (1981) discussed the health status of minorities by saying that the greater frequency of illness suffered by minorities is not due to greater susceptibility on their part but to the "result of economic, educational, environmental, and cultural handicaps

imposed directly or indirectly on minorities." She discussed the issues of socioeconomic status, environment, and, particularly, the failure of the health care system in the U. S. to correct these problems.

Conrad and Kern (1981) used the term social epidemiology to identify the inverse relationship of disease and economic status (the poor have greater incidence of disease). In that same text, Syme and Berkman's (1981) article suggested that lowered socioeconomic status results in greater susceptibility to diseases because of compromised defenses but that such a relationship must be proven by systematic research. No studies of renal disease could be found which have proven such a relationship.

Dohrenwend (1973) studied the relationship of stressful life events to psychological distress in persons of low social status. Her exploratory study used data collected from 124 heads of families. Using educational preparation as the independent variable (less than high school graduate vs. high school graduate or more), she created the two categories of high and low social status individuals. She hypothesized that persons of lower social status had more life changes than persons of higher social status. Using a list of stressful life events, her research associates asked subjects how many of the listed events they had experienced during the past 12 months. Using Langner's psychiatric screening inventory, they then measured the number of psychosomatic symptoms the person had experienced during that time. As hypothesized, the lower social status groups reported more stressful life events leading to a positive correlation between the two variables.

They also used sex and ethnicity as variables resulting in findings that stressful life changes are linked with social and sexual status but

not with ethnicity. Specifically, there was no evidence of higher levels of stress and psychological distress among blacks based on social status. Since blacks reported fewer stressful life events, this finding may be limited by the measurement of life change events that had no particular relevance to the individual; the inventory measured the occurrence of specific major events rather than other ongoing stressors of day-to-day living.

Rainwater (1974) wrote about the lower class in relation to health, illness, and use of medical services. Using various examples of others' research, he defined the lower class in regard to their bodies, medical treatment, and medical institutions. From his primary assumption that lower class people have different images of themselves, have different styles of coping, and live in constant crisis, he described how they interact with the health care system. He described the lower class as being resigned to illnesses, to diseases occurring in their bodies, and to using the health care system in a crisis-like manner.

A major question about this behavior is whether it is intrinsic to the lower class or whether it results from the behaviors they have encountered and lessons they have learned from the health care system. While Rainwater's observations appear to have validity, his assumptions about the lower class were not referenced or validated by any of his own or others' research studies. A second major question that remained unanswered in his writing is whether his assumptions should be attributed to class, education, ethnicity, or culture.

Snow (1974) explored the issue of folk medicine beliefs in the black culture. Using an ethnographic approach, she identified multiple facets of the system of folk medicine beliefs. Her work, however, confounds the variables of ethnicity and class; she studied only poor black adults.

Kleinman, Eisenberg, and Good (1978) expanded this concept of folk medicine and described the role that it still holds in the care that many patients seek today. Harwood (1981) provided a model for incorporating the health beliefs and behaviors of various ethnic groups into the delivery of mainstream health care thus allowing both for understanding and continuation of their own beliefs.

More recently, the issues of ethnicity and social class have been researched and reviewed in a different fashion. With increasing emphasis on the cost of health care provided by government programs, the groups who are receiving this care are being scrutinized. Bombardier, Fuchs, Lillard, and Warner (1977) conducted a study to describe access to surgical operations following the introduction of public programs which were intended to provide greater equality in access to health care.

Using data from the Health Interview Surveys for 1963 and 1970, they performed linear regression analysis and found that differences in surgical utilization were best explained by the variable of income level; race, residence, and education were not significant. In addition, there had been improvement in access from 1963 to 1970 especially for the most disadvantaged; the authors attributed this to the establishment of the Medicare/Medicaid programs during that time interval. Of interest in their research was the consistent finding that higher-income groups had more surgeries than lower-income groups but that higher-education groups had fewer surgical procedures. This finding seems to support the premise of a strong positive relation between health and education and a weak negative relation between health and income. This verifies the earlier work of Berkman and Syme.

Wilson, Griffith, and Tedeschi (1985) studied the relationship of race and hospital use. Using a patient sample in Michigan from the year 1980, they analyzed hospital use based on patient days and discharge data using five independent variables in the first model and four in the second; the first model analyzed community and health system variables while the second analyzed four community variables. Calculating correlations between whites and non-whites, their findings showed that racial inequalities have been substantially reduced but poverty, education, and age continue to correlate with significant differences in hospital use.

Blendon, Aiken, Freeman, and Corey (1989) showed that this trend may have reversed. Using data collected from a national telephone survey conducted in 1982, they compared the utilization of health care services between blacks and whites. Their findings indicated that blacks had less access to physician care as evidenced by fewer physician visits, had less insurance coverage, and received more of their care through public hospitals, clinics, or other organized settings. They also found that almost half of the blacks they surveyed received care via a public hospital or clinic on a crisis or symptom-related basis compared to only 25% of the white population surveyed.

The study by Wenneker and Epstein (1989) also identified inequalities in the access of black patients to treatment for ischemic heart disease in the state of Massachusetts during the year of 1985. Using discharge data, they determined that there was a significant difference in the use of angiography and coronary artery bypass surgery based on black/white racial differences. Using a logistic regression method, this study controlled for all possible confounding variables. In

controlling for income, the researchers determined that the interracial differences became statistically insignificant indicating that the real difference was in socioeconomic status rather than ethnicity itself. However, this data may be particularly biased by the exclusion of the VA Hospital system from the data base and analysis; since those facilities provide care mainly to males who are at higher risk of cardiac disease, this data seems especially valuable to the analysis; its exclusion considerably weakened the results of the study.

Blendon et al. (1989) also noted that blacks were significantly more likely than whites to experience changes in providers in the course of their health care thus making long-term planning difficult or impossible. This phenomenon could have a major impact on the ability of the patient to undertake appropriate decision-making processes about treatment.

Greenberg et al. (1988) have taken a different approach to analyzing use of health care services; in their analysis of treatment of lung cancer in two rural communities, the authors determined that socioeconomic factors as well as medical circumstances influenced the treatment regimen. Specifically, they determined that type of insurance coverage, marital status, and proximity to treatment facilities had significantly affected the choice of treatment. Some of their variables may have served as proxies for socioeconomic status and thus reflected the inequities in medical care for the poor and isolated.

Chassin et al. (1986) identified geographic differences in the use of services by Medicare recipients (all over age 65) in 13 areas of the U.S. For 1981, their results showed major geographic variations in rates of use of both medical and surgical procedures. The authors were unable to explain their findings but warned against the use of this data for

restricting access to care in those areas that seem to have over-utilization until better explanations can be made for these differences.

These studies identify the proposition that socioeconomic status, race, education, and other demographic variables may all play a role in the access to and use of health care services in the U.S. These studies span a significant period of time (more than 20 years) and illustrate both improvement and subsequent deterioration in the availability of health care for the disadvantaged.

Of particular relevance to the ESRD patient, Kasiske et al. (1991) have recently published a study on the effect of race on access and outcome in organ transplantation. Following a number of sensational reports in trade journals and the mass media which framed this problem within the context of racial discrimination, this review of transplant data in the U. S. noted that fewer minority transplants have been performed due to lack of compatibility in tissue matching; the lack of minority donors decreased the possibility of compatibility with the potential minority recipient. They also cited factors of increased drug and alcohol abuse, poor compliance with medical therapy, financial considerations of restricted funding through Medicaid programs, education, language, and cultural factors in the discrepancies in minority transplantation.

Importantly, these researchers concluded that all the factors except tissue compatibility actually reflected socioeconomic conditions rather than racial factors; however, these socioeconomic factors were not quantified in this report. They also noted that there are potential biases in transplantation related to a patient's socioeconomic status but denied overt discrimination against blacks.

A specific weakness in this study is that there is no mention of women's transplant potential; gender differences were not reported. This oversight is especially relevant because of Kjellstrand's previous findings of presumed discrimination against women relative to renal transplantation. Based on their findings, the authors recommended that health care providers should assume a greater responsibility for providing patients with sociocultural and economic disadvantages more education about and improved access to the modality of transplantation.

It is of interest that the Medicare-funded ESRD program collects no socioeconomic data about this patient population; because these benefits are not currently linked to financial need, there has apparently been no need to acquire this information. No major epidemiologic work or other disease investigation has recently been carried out on the beneficiaries of the ESRD program; similarly, no information other than age, sex, ethnicity, and reported diagnosis are known about this population of more than 170,000 patients.

Summary and Conclusions

The role and effect that the ESRD patient's ethnicity, culture, and socioeconomic status have on his/her access to and care in the ESRD Program have been poorly studied. Access to health care remains a major determinant of what will be available and offered to patients. The components of the framework for access to care and the sociocultural and demographic variables reviewed in this section identify the complex nature of the health care delivery system that exists in the United States. Only when patients have accessed the system in some fashion can they begin to make decisions about the care and treatment of their disease.

After access is established, patients are able to establish a relationship with health care professionals, usually with physicians. Access to the system, however, may be affected by sociodemographic variables which might create situations of advantage/disadvantage for patients.

The theories of and research on patient decision-making are based upon either a newly established or existing physician/patient relationship. Many commentaries describe the effect that the physician/patient relationship has on the decision- making process; most of these commentaries describe how the physician/patient relationship and interaction should be rather than how it actually is. Several research studies, however, have attempted to describe patient decision-making within the context of the physician/patient relationship. Patient satisfaction and agreement with a therapeutic regimen have often served as the measured variables which describe patient decision-making.

Other quasi-experimental studies have tried to enhance the physician/patient relationship and the decision-making process by having another party increase patient education and empower the patient before he/she interacts with the physician. Such studies have reported that they improve the outcome of the physician/patient interactions relative to the patient's well-being or outcome although one study does report that the interactions were worsened.

For the patient with renal failure, access to the treatment system is dependent upon the physician who serves as gatekeeper. The relationship that the patient has had or forms with the physician provider determines whether he/she will be referred for treatment, what options for treatment will be made available to him/her, and what decisions or choices

the patient will have to make regarding his/her treatment and continued life.

In the ESRD Program, very little has been reported about how patients access the system and how the patient makes decisions about therapies. We do not know who really makes these "patient" decisions. What role do the physician, other professionals, the patient, and his/her significant others play in the decision-making process? Is the treatment chosen the best choice for the patient, the health care system, and society? These questions about the ESRD System and its patients need to be answered to assure that this program is truly providing the best care possible for these individuals.

Discussion of Concepts/Theories

The theories and concepts of professional (medical and nursing) decision-making, patient decision-making, and access to health care particularly as they are influenced by sociodemographic, ethnic, and cultural variables which has been reviewed for this study have not been integrated into one theoretical framework or model. No study could be found which measured all of these aspects as they impact on the process of patient informed consent for care.

The President's Commission did identify all of the variables as critical to the definition and process of patient informed consent. Thus, it is that broad definition of informed consent which underlies this research.

Assumptions

Persons with chronic renal failure are a unique population whose fatal disease can be effectively treated by various medical technologies.

Their renal disease and its progression can be easily diagnosed by physicians using routine blood and diagnostic studies; renal disease associated with other primary diseases such as diabetes or hypertension can also be identified by blood and other diagnostic studies (Brenner & Rector, 1976; Friedman, 1978). Continued medical care can be provided to maximize patient well-being and renal function as long as possible before replacement therapy is initiated. All the resources of the health care system can be utilized to achieve these goals in patient care.

Because patients with chronic renal disease may be aware of their diagnosis, they can be informed and educated about their disease and its progression. These patients can be informed and educated about the treatment options available to them for replacement therapy and make rational decisions about the treatment they prefer before it is required.

As previously described, however, a number of patients will not be diagnosed early in the course of their renal disease and thus will not have the opportunity for the information, education, and decision-making about treatment which might be available to those patients who were diagnosed early. Because the ESRD system has not collected information about these two different groups of patients (diagnosed or not diagnosed early), there is only anecdotal or personal impressions about why or how this phenomenon occurs. Friedman (1978) reported that 40-70% of patients may have been aware of their kidney problem prior to it becoming very serious (near end-stage); he reported that only 50% of the patients in his university-based practice were previously aware of their renal disease prior to reaching their end-stage condition. The primary assumption regarding this population and their entry into the ESRD program is that their prior care, their understanding of their illness, and their need for treatment is quite varied.

Research Question

The primary research question being asked in this study is whether and how patients do make decisions about treatment for ESRD and what variables influence their decision-making process as it culminates in informed consent for treatment. Do patients recognize their methods and process of decision-making and informed consent for ESRD treatment as a special activity? Can these patients identify any specific variables or circumstances which influence their decision-making and informed consent?

Particular attention in this research will be paid to sociodemographic variables which may affect the patient's access to and involvement in his/her health care, what information and education the patient receives prior to initiating treatment, and who and what is recognized as influencing the patient's decision-making process.

Specific questions to be explored in this study include the following:

1. Can patients identify the variables that affect their access to ESRD care?
2. Can patients identify whether or not they made a decision (as reflected in their informed consent) about their choice of ESRD treatment?
3. Can patients identify variables in their relationship with health care professionals that influenced their decision-making about treatment?
4. Can patients identify other variables in their personal lives that affected and/or influenced their decision-making process?

CHAPTER III

METHODOLOGY

Research Design

This exploratory descriptive study sought to identify the process of decision-making and informed consent that a patient uses in choosing a treatment modality for ESRD. In the interviews, the patients in this sample were asked a series of questions about their sociodemographic identity and a second series of open-ended questions identifying their experiences in decision-making about ESRD treatment as well as their initiation of treatment.

Description of Research Setting

This research was performed in 33 ESRD facilities throughout northern California. These facilities were chosen because these were the treatment sites of patients whose physicians had given consent for interview. These facilities are representative of the various organizational structures providing care to the ESRD patient. Sixteen (16) of these facilities provided hemodialysis treatment only at that site while 17 facilities provided both hemodialysis and peritoneal dialysis treatments.

Interviews were performed in both free-standing proprietary (for-profit) and nonproprietary (non-profit) dialysis facilities. Five (5) hospital-based and owned facilities were sites for interviews (4 are associated with university health care teaching programs); 2 of these facilities are located in and are a service provided by county hospitals.

One (1) Veterans Administration hospital dialysis facility was included. One (1) renal transplant facility was also a setting for patient interviews. The geographic location of these facilities which also reflects the general residence of these patients is shown on a map in Appendix C.

Patient Sample

A convenience sample of adults (persons over age 18) was utilized for this study. Sample size was determined for this study by power analysis which indicated the need for a minimum sample size of 120; this sample size allows for statistically significant analysis of the sociodemographic variables obtained. A total of 150 patients participated in this research study.

The only limitation to participation was the requirement that the patient had to have been receiving ESRD treatment (one or multiple modalities) for less than 3 months at the time of interview. This criterion was used to assure that the patient had maximum recall of the events and circumstances regarding his/her care prior to the initiation of treatment. Carrying out these interviews as soon after initiation of treatment as possible theoretically minimized the possibility that patients would distort or forget the prior events of their medical care over a longer period of time.

This time frame of 3 months also correlates with the 3-month waiting period prior to initiation of ESRD Medicare coverage for outpatient hemodialysis. This waiting period is based on an original assumption incorporated into PL 92-603 that patients who suffer from acute renal failure and regain function will do so in a fairly short period of time.

This waiting period provision thus presumably prevented Medicare payment for an acute medical condition for patients who were not already Medicare beneficiaries.

Because of the route of diagnosis of renal failure and entry into the ESRD treatment system that a patient might undergo, these differences were identified by specific questions in the structured interview; the patients' responses to these questions indicated whether or not they had prior knowledge of their renal disease and need for treatment.

The structured interview questions included personal and demographic data as reported by the patient or surrogate, the patient's prior medical history and renal disease, ongoing medical care, and a series of questions relevant to their information and understanding of ESRD treatment modalities. The interview outline is included in Appendix D.

The patients participating in these interview were deemed competent to understand this research and sign the appropriate consent form. The researcher asked the nursing staff caring for the patient to verify his/her ability to participate in an interview; nurses were also asked whether the patient had signed his/her own consent for ESRD treatment.

Because the adult population of dialysis patients includes persons who are not competent to give consent for themselves, the participation of these patients was made possible through the consent and participation of their surrogates in the interview process. Two (2) patients included in this study had legal surrogates who agreed to participate in the interview.

Consent for this research study was obtained from the University of California San Francisco Human Subjects Committee; the consent form approved by that committee is found in Appendix E. In addition to the

consent form required by the researcher's own university, two other Human Subjects Committees required specific applications to their committees and separate consent forms (Appendix F).

Access to this patient sample was achieved through the consent of the patient's ESRD physician. To ensure the possibility of an adequate sample, letters were sent to 198 physicians in northern California who might be caring for patients receiving hemodialysis, peritoneal dialysis, or renal transplantation. The letter described the intent and design of this study and asked for consent to interview patients in their care. A stamped, addressed postcard indicating their consent or refusal was included for return to the researcher.

From the first mailing, 92 physicians gave consent to the interview of their patients by returning the postcard. A second mailing to nonrespondents was accomplished approximately 3 months later; an additional 15 physicians gave consent in response to that mailing. Thus, a total of 107 physicians gave consent for patient participation. Thirteen (13) physicians specifically refused to allow their patients to be interviewed while 7 physicians asked for further information before giving consent. A total of 39 physicians did not respond to either mailing.

Potential subjects were identified by administrative nursing staff in the dialysis or transplant facility. Arrangements were then made for an appropriate time to interview the identified patients/subjects.

A small group of eligible subjects were excluded from this research; these were patients who had received information and counseling about ESRD treatment from this researcher in her professional job activity. It was felt that her interview of these patients would result in biased

responses; no other individual could be identified who was willing to interview these patients.

Data Collection Methods

Data were collected by personal interviews with all subjects. The researcher individually performed all interviews using the structured set of questions. All answers were recorded in writing on the interview form by the researcher during the interview. Audiotaping of these interviews was planned but the environment of the dialysis units which limited appropriate placement of the recorder and the need for softer conversation to maintain some element of privacy made adequate recording impossible.

The structured interview (Appendix D) was conducted with each subject or surrogate participating in the study. The structured interview technique was chosen as the method of data collection for several reasons including the literacy level of the subject, the difficulty in writing during hemodialysis (when two needles are in place usually in the distal arm which could easily be displaced by writing movement), unfamiliarity with the English language, and the qualitative nature of many of the questions.

The structured interview included questions about the personal identity of the subject including age, sex, ethnicity, marital status, educational level, employment status, income, religious preference, and health insurance coverage. Information about the person's knowledge of any primary diseases, cause and length of renal disease, and their health care delivery prior to initiating treatment was collected from all subjects.

Groups of questions then were asked about the methods by which subjects became informed about their disease and their treatment options, previous experience with or knowledge about ESRD, how families, friends, or other colleagues were involved with the patient's decision-making, and what influenced their decision-making process. Because patients may or may not have known of their impending renal failure prior to initiating treatment, the questions relevant to the process of obtaining information and making decisions about treatment differed relative to timing and setting of their preparation about treatment. By virtue of these differences in knowledge about their disease, two groups could be identified by the interview process, those who had prior knowledge of their renal disease and those who indicated that they did not know of their disease state.

The strength of this research lies in the fact that this is the first study performed that attempts to identify the variables that may affect or influence the ESRD patient's decision-making process as it results in choice of treatment and informed consent for that treatment. Because there are no tools to measure this decision-making process, the structure of the interview may or may not have measured the decision-making process. To increase the validity of the responses, the selection of subjects to be interviewed who were new to treatment was intended to increase their accurate recall of their pre-ESRD treatment experience and to reflect the current influences and status of the health care system in regard to ESRD care.

Data Collection Procedure

Patients participating in this research were offered the option of being interviewed in a setting other than the treatment facility. For

purposes of convenience, two patients chose to be interviewed in their homes. All other interviews were conducted in the dialysis or transplant facility.

Patients undergoing hemodialysis treatment sit in a lounge-type chair with a hemodialysis machine next to the chair; the chairs and patients are in close proximity to the other patients in an open room. On rare occasions, the patient is in a smaller room (an isolation-type room) alone during dialysis and the interview. In addition, various staff were performing tasks of patient care during the interview period. On several occasions, the interview was accomplished in the patient waiting room of the facility before the dialysis treatment was initiated. These settings were neither private nor confidential; however, no patient chose to terminate the interview because of the setting and its lack of privacy.

This researcher performed all of the interviews. She identified herself as a doctoral student from the University of California San Francisco School of Nursing and wore a name tag at all times while in the treatment facilities. On some occasions, the researcher was formally introduced to the patient by a staff member in the facility. More frequently, the researcher introduced herself to the patient. She explained the nature of the research and asked the patient if he/she wished to participate. The consent form was given to the patient for reading and signature; if the patient indicated that he/she was unable to read it for a variety of reasons, the researcher would read it to the patient before signature.

Only four patients who met the criteria for interview refused to participate when approached; three were male and one was female. Two patients included in this research were represented by their legal

surrogates; one was a spouse and the other was a parent. All other patients were apparently legally competent to participate in this research; according to nursing staff, all had signed their own consents for ESRD treatment.

If the patient was interviewed during the hemodialysis treatment, the researcher sat on a chair/stool in close proximity to the patient so that some degree of privacy in the subject's responses could be maintained. All responses were recorded in writing as the interview was proceeding. The researcher occasionally paused in the interview to record a specific direct quotation from the patient because of its richness in expression and feeling. If patients was not receiving hemodialysis but were undergoing CAPD, they were interviewed in other rooms/offices in the dialysis facility. The two patients who were interviewed in their homes were performing CAPD treatment.

Data Analysis

Data analysis was performed by the researcher using both quantitative and qualitative techniques. The demographic data was numerically coded for each category chosen by the subject. All yes/no questions were numerically coded. Responses to the qualitative (open-ended response) questions generally followed a pattern of common themes. Thus, these were also numerically coded to allow for analysis of frequency of response. The quantitative responses were entered into the Crunch database for statistical analysis. Data analysis was performed for the entire group of 150 patients with Chi square analysis performed for statistically significant differences.

This data was also coded using the independent variable of the patient's perception of treatment choice as identified by a yes/no response to a specific question in the interview. Specific socioeconomic and health care dependent variables were identified for this analysis. The patient groups were coded as Group A ($n = 54$) for those patients who felt that they had a choice; Group B ($n = 46$) consisted of those persons who did not believe they had a choice of treatment modality. Both Chi square and regression analysis were performed using the Crunch statistical analysis program to identify differences between these two groups and the influence of these variables on patient choice of treatment.

CHAPTER IV

RESULTS

Over a period of approximately four months, this researcher interviewed a total of 150 patients who had been receiving ESRD treatment for 3 months or less. These interviews yielded data and information about these 150 patients which could be quantified. Following the first set of questions which yielded the demographic data, the questions that were asked about the patients' experience of learning about their renal failure, the treatments available to them, and how they made decisions resulted in an event for many patients that was more intense than a simple interview.

By asking open-ended questions about these patients' experiences, this researcher discovered that she provided the opportunity for these patients to tell their "story." The emotions that were expressed ranged from total satisfaction with their experience to total anger and frustration. Perhaps the undivided attention that these interviews provided to the patients during an emotional time (the early weeks of treatment) and the confidentiality promised in regard to what they said made it possible for these patients to respond in such an apparently honest and intense fashion.

Demographic Data and Results

The first analysis performed on the data collected in these interviews attempted to identify the demographics of this sample population (see Table 1).

Table 1

Patient Demographics (N = 150)

Mean Age	60
Gender:	
Male	81 (54%)
Female	69 (46%)
Race:	
White	90 (60%)
Black	31 (21%)
Hispanic	16 (11%)
Filipino	6 (04%)
Oriental	4 (03%)
Other	2 (02%)

As noted previously, the ESRD Program collects minimal sociodemographic data about its beneficiaries. To the extent possible, the data from this convenience sample can be compared to the ESRD patient population (N = 2243) receiving treatment in northern California ESRD Network #17 in 1990 (1991). A single mean age was not reported for the patients undergoing ESRD treatment in this geographic area. The USRDS (1990) did report that nearly 40% of new ESRD patients in the year 1988 were over age 64. Thus, the mean age of 60 found for patients in this sample suggests that it is a reasonably accurate reflection of the ESRD patient population.

Gender distribution of the Network #17 ESRD population in 1990 reflects that 54% were male while 46% were female which is exactly the same distribution as found in this research sample. The most recent USRDS report did not describe gender distribution except as adjusted by age, disease, and ethnicity so no accurate comparison can be made to the U. S. Medicare population.

The racial (ethnic) classifications used for this research are those used for the most recent U. S. Census. However, the ESRD program uses different classifications to gather racial data about ESRD Medicare recipients. The data from Network #17 for 1990 showed that 50% of all patients receiving ESRD treatment in northern California in 1990 were white; 16% were black; 10% were Asian/Pacific Islander; 22% were other; and 1% were Native American. The sample of this research study identified a slightly higher incidence of white patients as well as a higher incidence of black patients from those Network figures. Other comparisons cannot be made due to differences in racial (ethnic) classifications used. The USRDS data report (1990) reported that 67% of the Medicare ESRD population in 1988 was white while 29% were black, and the remaining 4% were of other races. The ethnic distribution of this sample is similar enough to both the network and national data to consider it representative of the ESRD population.

In summary, with the exception of data on ESRD patient age in northern California, the demographic variables of sex and ethnicity identified for this sample of 150 patients is very similar to the population of patients undergoing ESRD treatment in 1990 in northern California. While the ethnic distribution is not exactly comparable due to greater specificity in ethnic classifications used for this research, these distributions seem comparable. This demographic similarity strongly suggests that the sample used for this research study is representative of the ESRD patient population in northern California and perhaps even of the national ESRD population.

Socioeconomic Data and Results

Educational Level

Questions regarding the patients' socioeconomic status were asked to determine whether the variables of education, employment status, and income might be related to their decision-making about ESRD treatment. Again, this information was obtained from patient self-reporting; the responses to these questions were recorded without verification by others or from the patient's medical record. Responses were incomplete for the categories of educational level and employment status. Tables 2, 3, and 4 summarize the results of questions about these variables.

Table 2

Educational Level (n = 149)

LEVEL	#	%
None	4	(03%)
Grade School		
Attended	11	(07%)
Completed	11	(07%)
High School		
Attended	26	(17%)
Completed	42	(28%)
Technical School	12	(08%)
College		
Attended	21	(14%)
Completed	18	(03%)
Post-Graduate	4	(03%)

No data is available to compare the educational level of participants in this research to the larger population of ESRD patients. It is fairly clear that this is not a highly educated group of patients. Seventeen percent (17%) of patients had a grade school education or less

while 46% had attended or completed high school. Twenty-nine (29%) had attended or completed college or postgraduate education. The more advanced age of this population may be a contributor to the educational level measured in this sample.

Employment Status

In questioning patients about employment status, the patients were asked to indicate their usual employment status and activity before starting ESRD treatment and without the effect of becoming acutely ill.

Table 3

Employment Status (n = 147)

Status	#	%
Retired	73	(50%)
Currently Employed	32	(22%)
Unemployed	5	(03%)
Short-term Disability	14	(10%)
Long-term Disability	23	(16%)

Based on the mean age of the sample as previously reported, it is not unexpected to find that almost half of all patients interviewed reported themselves as retired; the ESRD program in the U. S. is serving an older age group just as other specialties in the health care system are doing. Of interest is that older women who participated in this study and who had never worked outside of the home also reported themselves as being retired; it was unclear from the data collected in this interview whether they were still performing their household duties. Few patients reported the need to "retire" as a direct result of their development of ESRD.

Simple mathematical calculation indicates that the 5 unemployed patients would reflect an unemployment rate of 6% based on a potentially employable population in this sample (86 patients under age 65); this is comparable to the general unemployment rate which has been reported in the popular media during the time period of this research.

Short-term and long-term disability status as related to previous employment were both frequently reported. Because these interviews were conducted during the first 3 months of ESRD treatment, a short-term disability status that had been initiated shortly before treatment was begun would still be in effect; a total of 14 patients indicated that they were currently on short-term disability leave from their current jobs but were apparently planning to return to work.

A total of 23 (15%) patients in this sample indicated that they were receiving long-term disability. This number is not unexpected given the incidence of other primary diseases, particularly Type I Diabetes Mellitus, which result in ESRD. As will be reported in a subsequent table, this disease is the leading cause of ESRD in this sample. For those patients who have developed visual loss as a complication of their diabetes, continued employment may become difficult or impossible. In addition, the anemia which develops because of and prior to the onset of ESRD may render patients unable to continue their full-time employment.

While specific information was not obtained about the determination of disability status by patients or their physicians, one gentleman did report that his physician told him that he would have to quite working because of his kidney failure. Although he was elderly, he had maintained his own shoe repair business for his entire adult life and expressed some concern about having to quit work. He was unclear about why his physician

felt it was necessary but was in the process of following his physician's instructions by selling his business when he was interviewed.

Another young man reported that he had been forced to quit work when he became ill because of lack of health care insurance; to qualify for Medi-Cal coverage without an exorbitant share-of-cost, it was financially necessary for him to leave his job. This young man had no health care coverage through his employer and also had no individual health care coverage.

In summary, it is clear that a number of factors impact on ESRD patients' employment status, including age and physical status. Continued employment by patients may also be influenced by the advice of their physicians prior to initiation of treatment. The physician who feels that the elderly patient should no longer have to work may give advice that fails to recognize the patient's abilities or desires. Do physicians encourage the disability status of patients who are developing renal failure by suggesting that they quit working and by offering them disability status through physician verification? What value is actually placed on continued employment of the ESRD patient by members of the health care system and/or employers and health insurance companies?

Finally, the role that health insurance coverage plays in the employment status of the ESRD patient both at the time he/she initiates treatment or as the patient seeks employment after treatment has begun is poorly understood. The patients' comments regarding concerns about employment status that they provided during the course of these interviews suggests that this is an important issue for ESRD patients.

Income Level

To complete the data base about socioeconomic status, patients were asked what their income was for either themselves or their household (whichever the subject felt was relevant) for the year prior to the initiation of ESRD treatment. Because this question was viewed as one of the most private and sensitive, the subject was not asked for specifics of income, i.e., gross or net income but was asked to choose from a range of incomes given in $10,000 increments.

For purposes of the reporting data in the following table, several of the income ranges are compressed because of the small number of responses in those categories.

Table 4

Yearly Income (N = 150)

YEARLY INCOME	#	%
$ 0 - 10,000	55	(37%)
10 - 20,000	34	(23%)
20 - 30,000	24	(16%)
30 - 75,000	16	(11%)
75,000+	5	(03%)
No Response	16	(10%)

Only three patients actually refused to reveal their incomes; by employment status or other information provided during the interview, however, it was clear to the researcher that the income of these patients was at the upper range of the scale. The other patients in the no response category responded that they did not know what their income was.

Because the ESRD Medicare Program is an entitlement program, patients are not required to reveal their income. Thus, the Medicare Program does not collect any data regarding the economic status (income level) of ESRD beneficiaries. Social workers may obtain this information as part of their assessment and may or may not keep it confidential.

Only one patient reported having to supply to a social worker a complete financial history including income, savings, property ownership, etc. before beginning dialysis. She expressed concern during the interview that she believed this was essential because she would have to pay for her ESRD treatment. She stated that she was very concerned about payment for treatment and would not have initiated dialysis if she would have had to sell her home or decrease her family income appreciably. She also reported that she was not immediately advised that her own health care insurance would likely cover the costs of ESRD treatment; she reported that she was not told about the Medicare ESRD Program or other health insurance coverage for ESRD at the time of her diagnosis and medical discussions about dialysis treatment.

Several elderly patients living with their children reported that they had no income of their own; other retired persons reported primarily receiving only Social Security retirement benefits; in answer to the question, they would report the exact amount of their monthly checks. Similarly, patients on long-term disability would report the amount of their monthly checks. While it is possible that these patients had higher incomes than reported, it seems unlikely to this researcher based on the candor and lack of hesitancy in the patients' responses to this question.

The renal disease patients in this sample reflect a generally lower socioeconomic status in U. S. society. In part, this appears to be due to the greater number of patients who are retired and living only on Social Security benefits or those living on long-term disability payments. This data cannot be construed, however, to show a cause and effect relationship between the income status of the patient and the medical diagnosis of ESRD.

None of the variables reported in this section could be compared to either regional (northern California) or national ESRD patient data because none of these variables are collected by the ESRD Program.

Family Relationship/Social Support Data and Results

A group of questions in the interviews were included in an attempt to measure family relationships and social support variables. These questions asked about patients' marital status, family relationships, relationships with significant others, and their living arrangements.

Marital Status

The advanced age of patients in this sample may explain the percentage of married and widowed patients undergoing ESRD treatment; 69 of 150 patients were married while 28 reported that they were widowed. Thirty-five (35) patients reported that they were single while another 18 patients reported that they were either separated or divorced. No patients reported that their separated or divorced status was directly related to the initiation of ESRD treatment although a few patients reported that their marriages had ended due to prior medical status or illness (e.g., diabetes). Marital status changes related to the development of ESRD were not found in this research.

Family Membership/Closeness

Patients were asked to identify their closest family member without specific definition of what that phrase meant. The reason for this approach was to obtain as spontaneous and honest an answer as possible to reflect this aspect of social/family support. Thus, the participants were simply asked to identify whom they considered their closest family member.

An interesting, but unexplainable, finding is that many older married adults did not identify their spouses as their closest family member; rather, they indicated that an adult child was their closest family member. In addition, some married males identified their mothers as their closest family member although no married women identified their mothers as their closest family member.

Presence of Children

Because of the marital status and the more advanced age of patients in this sample, it is not surprising to find that a majority of the entire sample had offspring. A total of 111 patients (76%) of the sample reported that they had children. In addition, 90 (81%) of this sample reported that their children are adults while only 14 (13%) patients reported that their offspring were under the age of 18. Thus, many of the patients who reported that their closest family members were children were referring to their adult children.

Living Arrangements

The inquiry about the living arrangement of these patients identified that many of them live with their adult children; 56 patients (37%) reported that they lived with a child. Fifty-one (51) patients reported that they lived with their spouses while the remaining patients lived either alone or with others.

In summary, adults have family relationships which often extend to shared living arrangements. These patients also frequently identified that their adult children were their closest family members even though they were also married. Even though this population was older and

Table 5

Family Relationships/Social Support

	#	%
Marital Status (N = 150)		
Married	69	(46%)
Single	35	(23%)
Widowed	28	(19%)
Separated	10	(07%)
Divorced	8	(05%)
Closest Family Member (n = 148)		
Child/Children	49	(33%)
Spouse	42	(28%)
Sibling	21	(14%)
Parent	22	(15%)
Other	14	(09%)
Children (n = 147)		
Yes	111	(76%)
No	36	(24%)
Age of Children (n = 111)		
Adult	90	(81%)
Minor	14	(13%)
Both	7	(06%)
Living Arrangement (N = 150)		
Children/Extended	56	(37%)
Spouse	51	(34%)
Alone	31	(21%)
Significant Other	4	(03%)
Friend/Other	8	(05%)

suffered from a chronic illness, very few of these patients of these patients were in long-term care facilities at the time of interview.

Religious Affiliation Data and Results

Religious beliefs and affiliations may serve as a measure of social support as well as a reflection of patients' general beliefs about life and death. Religious beliefs and affiliations may also influence a patient's use of health care services and medical technology. The question about importance of religious belief was explained to the patient as its importance to their health care decisions.

More than 50% of the patients in this sample reported a religious affiliation. Approximately 66% of the patients who responded to this question reported that their religious beliefs were important to the decisions they made about health care. The results of the two questions asked about religion are summarized in Table 6.

Table 6

Religious Beliefs

	#	%
Religious Affiliation (n = 146)		
Protestant	62	(26%)
Catholic	39	(27%)
Jewish	3	(02%)
None	38	(26%)
Other	4	(03%)
Religious Importance (n = 82)		
Yes	54	(66%)
No	28	(34%)

Health Care Access/Utilization Data and Results

A series of questions were asked to determine the type of health care which these patients had been receiving prior to initiating their ESRD treatment. These questions attempted to measure the patients' access to and method of payment for health care as well as the type of health care they were receiving. These questions were specifically asked to measure health care delivery in the time period before ESRD treatment was initiated. Thus, these responses do not reflect the health care coverage that became available to the patient when ESRD treatment was initiated.

Health Insurance

The question about health insurance coverage specified that this was the coverage that the patient had prior to initiating ESRD treatment. Almost all patients (145) included in this sample had some type of health care insurance coverage prior to entering the ESRD Program.

Medicare recipients constituted 82 of the 150 patients in this sample; this frequency of patients having Medicare coverage is not unexpected given the more advanced age of this sample as previously reported. In addition, patients who had been receiving long-term disability benefits may also have qualified for Medicare benefits due to their primary chronic illness.

The small number of patients without any health care coverage can most likely be explained by the more advanced age of the patients in this sample as well as the fact that most of them had been receiving medical care on a regular basis.

Physician Management

A second issue of access to health care is reflected by whether an individual is seeing a physician on a regular basis. Of the 143 patients who responded to the question about physician care, 91 (64%) reported that they had been seeing a physician on a regular basis while 36% indicated that they had not been seeing a physician.

While the patients were asked to identify the specialty practice of the physician whom they were seeing and that data is reported in the table below, this information was not verified. This researcher believes that many of these patients were unclear in their understanding of their physician's specialty. Indeed, one patient was receiving care from a

nephrologist prior to initiating dialysis treatment but did not identify him as a nephrologist; she believed him to be a "general" doctor. The results of this information about health care access and services are summarized in Table 7.

Table 7

Access to and Use of Health Care

	#	%
Medical Insurance (n = 148)		
Private	41	(28%)
Medicare/Private	48	(32%)
Medicare/Medi-Cal	22	(15%)
Medi-Cal	20	(14%)
Medicare Only	12	(08%)
None	5	(03%)
Seeing MD (n = 143)		
Yes	91	(64%)
No	52	(36%)
Kind of MD (n = 67)		
General/Family	28	(42%)
Internist	25	(37%)
Cardiologist	5	(07%)
Diabetologist	7	(10%)
Don't Know	2	(03%)

Nephrology Management

All patients interviewed were asked whether they had been seeing a kidney specialist (nephrologist) prior to starting ESRD treatment. During the verbal interview, the term "kidney specialist" was used in speaking with patients to assure that they understood the type of specialist about whom the researcher was speaking. For those patients who responded that they had being receiving care from a nephrologist, a question was asked to determine the length of time that the patient had been seeing this

specialist. The time frame of this specialty care relative to initiation of ESRD treatment appeared to be completely random.

In summary, almost all patients in this sample had access to the health care system and the majority were seeing a physician (generalist and/or nephrologist) on a regular basis. A number of patients interviewed reported that they had been seeing both a generalist physician as well as a nephrologist. Some patients also reported that they had seen or been seen by a nephrologist on one occasion; these patients were not included in the group of patients reported here as "seeing a kidney specialist."

While patients in this study appeared to have few barriers to health care access due to medical insurance, access to specialty practice can influence how the patient understands his/her disease status or progression, how they will make decisions regarding future treatment, and what access they will have to others who may assist in their care and education. The following table summarizes how these patients reported their access to nephrology specialty care.

Table 8

Access to Nephrology Care

	#	%
Seeing Kidney Specialist (n = 149)		
Yes	70	(47%)
No	79	(53%)
How Long Seeing Kidney Specialist (n = 68)		
0 - 6 Months	24	(35%)
6 - 12 Months	16	(24%)
1 - 2 Years	10	(15%)
More Than 2 Years	18	(26%)

Patient Knowledge of Renal Disease

This series of questions were asked to obtain information about whether patients knew the cause their illness and/or whether they had been given their diagnosis in a way they could comprehend it. Patients were asked whether they knew the cause of their renal failure; if they responded affirmatively, they were asked to identify the cause (the medical disease or condition) by name or phrase and how long it had been present.

If the cause of their renal failure was another primary disease such as diabetes, its period of existence might not be synonymous with the presence of renal disease. Finally, all patients were asked how long they had known about their renal disease before starting ESRD treatment. In some cases, these two time periods could be the same depending on the cause or course of the patient's renal failure. Table 9 summarizes these results of the patients' knowledge of their renal disease.

When one considers the responses to these questions, it appears that the basic knowledge that patients have about their medical status/renal disease is lacking. More than 1/3 of the patients participating in this study did not know the cause of their renal failure; this is particularly significant when one recalls that almost all of these patients were receiving regular medical care. In addition, 1/5 (20%) of these patients did not know that they were developing renal disease until less than one month before initiating dialysis. As these are patients who are certified as having chronic renal failure, it would seem that there has been either a lack of communication or a misunderstanding on the part of the patient about his/her medical condition or status. While their renal condition

Table 9

Renal Disease Knowledge

	#	%
Know Cause of Renal Disease (N = 150)		
Yes	98	(65%)
No	52	(35%)
Cause (n = 103)		
Diabetes	42	(41%)
Other	30	(29%)
High Blood Pressure	17	(17%)
Auto Immune Disease	6	(06%)
Heart Disease	4	(04%)
Infection	3	(03%)
How Long Had the Disease (n = 104)		
More Than 20 Years	22	(21%)
11 - 20 Years	34	(33%)
6 - 10 Years	13	(13%)
1 - 5 Years	14	(13%)
0 - 1 Year	8	(08%)
Don't Know	12	(12%)
How Long Known About Kidney Disease Before Treatment (n = 123)	21	(17%)
1 Week or Less	4	(03%)
Less Than 1 Month	17	(14%)
1 - 6 Months	14	(11%)
1 - 2 Years	20	(16%)
Longer Than 2 Years	40	(33%)
Don't Know	7	(06%)

may have been exacerbated by another acute event or medical problem such as an infection, a myocardial infarction, or a necessary surgical procedure, these patients indicated that they were unaware that there was "anything wrong" with their kidneys before that event.

In addition, the responses that patients gave about the cause of their renal failure were often tentative or said without belief; patients would report their disease as being what their doctors told them. Distortions also occurred as exemplified by the woman who reported that it was the "blood pressure medicines" that caused her renal failure rather than her hypertensive disease.

Patient Information/Education about Treatment

After collecting the demographic data and general health care information reported above, the next questions were designed to elicit what the subjects recalled that they had been told about treatment, who told them, and under what circumstances they were told.

Fifty-four patients (36% of the total sample) indicated that they felt they had no prior knowledge of their renal disease/failure before having to initiate treatment. These patients described that their initiation of dialysis was sudden and was a shock to them; it was totally unexpected. A summary of the responses to two specific questions about how this event of diagnosis of renal failure on an emergent basis occurred is as follows:

1. Why did you go to the doctor? Of the 50 patients who were able to answer this question, almost half (48%) of them sought medical care because they were suffering from shortness of breath or severe swelling of extremities; 36% of them sought physician care because they "felt sick" while 14% had a primary complaint of nausea and vomiting; 2% sought medical care because of a severe, unremitting headache.
2. Did you go directly to the emergency room because you were feeling ill? Of 48 patients responding, 94% (45 patients) reported that they went directly to the hospital emergency room while only 6% (3 patients) went to a physician's office.

In an attempt to identify the informational process that these ESRD patients experienced, this interview specifically asked them to identify who told them that they would need ESRD treatment as well as who further explained or answered questions about treatment. While the questions

asked of patients who did or did not anticipate their renal failure were necessarily slightly different because of the circumstances they experienced, the patients' responses reflect similar interventions.

These patients' responses reveal a process of patient information and education about their impending ESRD treatment. These findings can be summarized in the following narrative fashion.

The 96 patients who indicated that they were aware of their renal disease were almost always told of their need for ESRD treatment by their primary physician (not necessarily a nephrologist) during the course of a routine office visit. No specific appointment or time was generally dedicated to a discussion regarding the patient's ESRD treatment.

Because these patients had an unspecified, but more extended, time period prior to initiating ESRD treatment, it can be assumed that more extensive patient education could be accomplished. To identify whether such education was available to these patients, patients were asked whether they had been referred to other professionals to discuss their ESRD treatment. Fifty-three (53) of the 96 patients (55%) indicated that they had not received any such referral; 34 patients (45%) reported that they had been referred to another health professional to discuss ESRD treatment.

When these patients were asked to whom (other than their physician) they had been referred or spoken regarding their ESRD treatment, a total of 87 patients indicated they had been referred to either a nurse, social worker, or dietitian. The patients believed that these health professionals were all nephrology specialists. Seventeen (17) patients indicated that they had spoken to a dialysis nurse; 5 spoke to a social worker; and 1 indicated that he had spoken to a dietitian. However, 32%

of these patients could not identify the professional to whom they spoke. The quality and content of these interactions were not measured in this study.

To identify the type of information or education that patients might have received either from their physician or another health care professional, they were asked whether they had been able to receive any written, audio, or video information about ESRD treatment. Of 89 patients responding to this question, 46 of them indicated that they had received one or more types of information. In addition, 17 patients of these patients indicated that they had spoken with another patient, a stranger to them, who was currently undergoing ESRD treatment. These meetings were arranged primarily by physicians and nurses.

Finally, 45 patients indicated that they had been offered the opportunity to visit a dialysis unit before initiating their treatment; 43 patients responded that they were not offered such an opportunity. Thirty-six (36) patients did visit a dialysis facility; 34 of them reported that it was helpful to see this environment while 2 patients did not find it beneficial. One of these patients reported that it was very frightening and depressing.

It is clear that educational opportunities are not made readily available to the potential ESRD patient by their primary physicians, through referral to other nephrology professionals, by making available various educational materials, or by establishing contact with other patients. Fewer than half of the patients who knew about their renal disease reported that they had been offered any of type of educational or informational materials or services.

Similar responses about their education or information regarding ESRD treatment was elicited from patients who had no previous knowledge of their renal failure. Because the majority of these patients presented acutely to the hospital and were advised of their renal failure and need for ESRD treatment at that time, the questions asked attempted to identify any education or information that they received during that hospitalization as well as who provided them with such information.

Fourteen (14) of these 56 patients reported that they received written or video information during their hospital stay. This information was primarily supplied either by a physician or a nurse. However, 12 of these patients reported that they received this information only after their dialysis treatment had begun. When these patients were asked whether they felt they had an opportunity to ask questions about treatment, 17 patients responded affirmatively while 16 patients felt they had not had such an opportunity. Eighteen (18) patients reported that they had asked their physician about treatment while 2 patients reported that they discussed ESRD treatment with their nurse.

It is important to note in their process of being informed about ESRD treatment, 11 of these patients reported that they had to undergo ESRD treatment the same day that they were told they needed treatment for their renal failure. Eleven (11) patients reported that they had to initiate treatment the next day. An additional 15 patients reported that they had 3 days or more before having to initiate treatment. Nineteen (19) patients could not recall the time interval between being advised that they needed ESRD treatment and initiating it in the hospital setting.

According to the responses obtained in these interviews, patients who initiate ESRD treatment acutely and without prior knowledge of their

renal disease also recall receiving little information and education about their treatment at the time of its initiation in the hospital. It is unclear whether such education is impossible to provide to patients during this time or whether it simply is not considered important.

A question to measure what patients recalled being told about ESRD treatment was asked to both groups of patients--those who knew about their renal failure and those who did not. Of the 96 patients who had the opportunity for education and information prior to initiating treatment, they reported being told the following: 25 patients said they were told they would "need dialysis"; 23 patients said they were told they would have to "go on dialysis"; 6 recalled being told they would need a "shunt or fistula"; 5 learned that their "kidneys aren't working/kidneys are shot"; 4 said they were told they would have to "go onto the kidney machine"; 2 were told they would need dialysis or transplant"; 2 were told that "dialysis is best thing for you"; 1 was told he would "need treatment for kidneys"; 1 related that the recalled being told "something was wrong with my blood"; 1 recalled being told would "need dialysis because your kidneys aren't working--let's see how your veins are"; and 1 recalled being told that the "last step is dialysis."

For those 56 patients who did not have prior knowledge of their renal failure, only 37 patients were able to answer the question about what they were told. Of these 37, 13 reported that they didn't remember much and or didn't understand; 11 reported that they recalled being told that they needed to "go on/be on/start dialysis or treatment"; 5 patients said that they weren't told anything; 3 recalled being told about types of treatment; 3 recalled being told they would have to have a "tube/catheter put in"; and 1 recalled being told that his kidney function might return

and that he just needed "backup." One elderly woman recalled that the "Dr. just said treatment--I thought it would mean one." In addition, 4 patients said that the physician talked to family members rather than them because of their medical condition.

Explanations of treatment modalities as reported by these patients in response to this question included the following: "tube in stomach and do four times a day seven days a week or have hemodialysis only three times a week" and "tube in arm--stick needles in"' another recalled being told that he would " have dialysis two or three times a week and that he was a "prime candidate for transplantation"; one patient recalled being told about dialysis and transplant with an emphasis on transplant because she has 4 brothers (presumably one could serve as a kidney donor). One described peritoneal dialysis as "a bag in the stomach" based on his understanding of that treatment modality.

One elderly patient recalled that he was told that he was being taken "to dialysis" and that it was "on the same floor--if I signed something, I don't remember." Another recalled that he was lying in bed and was "wheeled into a room and they gave me a treatment."

The drama of ESRD and its treatment was reported by three patients who recalled being told the following by physicians: "if I didn't have it [dialysis] done, I would die in 24 hours"; "I've got to have this treatment or I'll die---the Dr. seemed so serious I began to believe him"; finally, an 18 year old recalled being told that his "blood sample was not compatible with life; the Dr. asked about kidney function--not a lot of urine coming out."

Patients also volunteered on several occasions their lack of understanding about "dialysis;" one patient poignantly reported the lack

of definition and explanation that he received by saying "I didn't have the first idea about dialysis." Finally, one patient (who happened to be a secretary in a hospital department) summarized his recollections by saying "maybe they explained but I didn't understand anything about dialysis. The doctor kept asking me if I had any questions; I didn't have any because I knew nothing about it." This patient summarizes how little patients seemed to know about and understand the phenomenon of "dialysis."

From these comments, it appears that the explanations these patients received were framed as the type of access required or the time required for treatment. As one patient said, "they assumed I had general information."

Those patients who knew about their renal failure prior to treatment had the potential opportunity to obtain information. As reported previously, patients were asked whether they had received any information (written, video, or audio) before initiating ESRD treatment. Seventeen (17) patients reported that they had received the "blue" book; this is a description of the book WHEN YOUR KIDNEYS FAIL (Faris, 1981) which has been made available to all ESRD patients without charge through the National Kidney Foundation of Northern California. Its primary distribution route is to social workers in ESRD facilities and would thus be made available to patients only after treatment is initiated.

Nineteen (19) patients reported receiving a variety of pamphlets and brochures. Five (5) patients reported seeing a videotape (source unknown) about ESRD treatment and one (1) patient recalled receiving a booklet on peritoneal dialysis. Several patients qualified their responses to this question by saying that they never read the information they received. While this interview did not include a specific question about whether and

why patients may or may not have read written information provided, one patient said that she was too depressed about her diagnosis and her future to do so; another said that she was "too scared." One elderly gentleman volunteered that he never read anything other than the newspaper and business papers but volunteered that he would have watched a videotape if it had been available.

One very well educated patient reported that his physician, a cardiologist, made no information available to him. Because he wanted more information about dialysis before starting treatment, he had to contact the local chapter of the National Kidney Foundation who did supply him with written materials. Another patient who is a writer/journalist went to his local public library but the books they listed in the card file were generally unavailable. The one he obtained was quite outdated and provided him with some incorrect information.

During these interviews, several patients also noted that they did not feel that they had the opportunity to ask questions or discuss any of the information they had obtained with their physicians. None indicated that their physicians had asked if they had questions from the pamphlets/booklets they had been given.

Seventeen patients who reported having an opportunity to speak with a stranger (a patient currently undergoing treatment) were asked if and how it was helpful to them. Four (4) patients were helped by hearing from patients how they felt while they were receiving dialysis treatment, 2 reported negative impressions given by patients, 1 felt it helped him to know what to expect, and 1 reported that it was not helpful at all. Several patients indicated that they had been offered the opportunity to talk to a patient but were too scared to do so. Several also reported that talking to transplant patients was most helpful.

The benefit of visiting a dialysis unit prior to starting treatment was variable for the 21 patients who responded to this question. Seven (7) patients found it helpful to know what they would be doing when they came for treatment. Four (4) patients reported their fear of the unknown was relieved. Three (3) patients were pleased that the dialysis unit seemed to be a friendly, nice place. One (1) patient found it very depressing to see the facility and patients undergoing treatment. Finally, 6 patients chose not to visit the dialysis unit admitting that they wished to avoid seeing it or were too fearful to see it before beginning treatment. As patients described these visits to the dialysis unit, one described looking in when it was closed so no patients were receiving treatment. Others looked in to see the environment but did not talk with staff or patients. Apparently, these patients were instructed by their physicians to "drop by" to see the facility without formal arrangements being made with staff who could explain the environment and procedure to them.

In addition to the responses to these questions, 13 patients who knew about their kidney failure and had not had the opportunity to speak with another patient stated that they felt such a discussion would have been helpful to them.

Social Support and Family/Friend Involvement

Social support and the involvement of the patient's significant others in his/her decision-making process was measured by several questions in this interview. Again, the differences in awareness of their renal disease between patients makes some of the questions and their responses similar in meaning but not statistically comparable.

The involvement of family or significant others in supporting the patient, understanding renal disease and its treatment, and assisting the patient in decision-making is enhanced if that individual also has knowledge and information. Only half (51%) of the patients who had prior knowledge of their renal disease reported that they were accompanied by a family member or friend to their physician visits; this researcher clarified that accompaniment meant being in the office during the patient/physician interaction rather than remaining in the waiting room. This question thus measured the frequency of another person being included in the discussions about ESRD treatment and hearing the same information given to the patient. Since many of these patients reported having marital partners and/or living in extended family situations, it is somewhat disturbing that family members are not included in discussions about ESRD treatment.

When patients who emergently learned about their ESRD were asked whether family or friends were present during the physician visits, 77% reported that they were. Presumably, these family members or friends were informed of the patient's renal failure and need for treatment simultaneously with the patient.

For the patients in both groups who indicated that a family member or friend was present during their physician visits, spouses and children were the primary family members included.

When patients were asked whether they had discussed their renal failure and need for treatment with family members, responses between these two groups of patients differed. Of 87 patients who were aware of their renal failure and who responded to this question, 77 patients indicated that they had told family members of their medical condition and

need for treatment while 10 patients indicated that they did not inform or discuss it with their family. In the acutely diagnosed group, only 17 patients reported that they discussed their medical condition and need for treatment with their family; 18 specifically reported that they had not done so.

The secrecy about ESRD and its treatment is a phenomenon that this researcher has noted throughout her clinical career. There has been no documentation of this aspect of ESRD in the literature although one might construe the patients' need for secrecy as a measure of their denial or protection from discrimination. Twenty-five (25) patients reported that they had kept their renal failure and need for treatment a secret while 69 patients did not feel the need to do so.

Patients reported during these interviews several reasons for keeping their disease and treatment a secret. Adults who were still employed (not on disability) tended to keep their renal disease a secret because they were afraid of losing their jobs. Some were afraid of having friends and colleagues "feel sorry for them" or "treat them differently." Males were more secretive about their renal failure than were females; while denying secrecy, they often reported that it "wasn't anybody else's business." Elderly patients (both males and females) tended not to keep their renal disease and treatment a secret as much as younger adults did.

Talking with people one knows is a common method of information gathering that many persons use. In addition to speaking with patients undergoing ESRD treatment, patients often have the opportunity to speak with other family, friends, or others via informal networks. Of the 12 patients who reported that they had talked with a person they knew who was also receiving treatment for ESRD, they did report how their conversation

was helpful to them. Five (5) patients reported that they were relieved to know what dialysis would be like; 2 patients reported that it generally helped them; 2 patients said that their friends recommended that they undergo treatment; and 1 was relieved to hear that the treatment was not really painful. One patient reported that her discussion made it worse while one other patient was told by her friend that she didn't like dialysis.

Two patients reported making great efforts to talk with people regarding their impending ESRD treatment. One young woman reported making cross-country telephone calls to a high school friend of hers whom she knew had also suffered from renal failure. She recalled that he was most supportive and encouraging to her about undergoing treatment. Another patient spoke via cross-country telephone calls with a physician friend who is not a patient; this friend seemed to have assisted him in understanding his illness and the dialysis treatment recommended. As these patients related these stories of gathering information, it appeared obvious that they had spent much time and energy trying to gather information. This patient work was done at a time when these patients were feeling most ill and had little additional energy to expend.

Personal Experiences and Decision-Making

As described previously, people died of kidney failure prior to the development and utilization of ESRD treatment modalities. With the use of ESRD treatment, life was sustained for patients for varying periods of time. During the past 20 years, several hundred thousand people have undergone dialysis and/or renal transplantation. Therefore, it is likely that persons diagnosed with ESRD might have had a personal life experience

with kidney failure which influences their perceptions and understanding about their own illness and its treatment. In addition, these persons may serve as a source of information (or misinformation) about ESRD treatment. Thus, these interviews included questions about personal experiences that the patient may have had in regard to kidney failure and its treatment. The responses to these questions are reported in the following table.

Table 10

Personal Experience with ESRD

	#	%
Ever Known Anyone With Kidney Failure (n = 134)		
Yes	60	(40%)
No	74	(60%)
Who Do You Know (n = 64)		
Family Member	28	(44%)
Friend	25	(39%)
Acquaintance	11	(17%)

When 39 patients who had been able to anticipate their need for ESRD treatment were questioned about whether they spoke with the person they knew about treatment, only 11 (28%) of them responded that they had done so. Of 24 persons responding to the question of why they had not spoken to that person they know, 20 of them (83%) indicated that the person was dead; only 4 (17%) did not want to speak with that person.

It was surprising to this researcher that two women who participated in these interviews had a very intimate knowledge of renal failure and its treatment. Both had husbands who had undergone dialysis. One was an elderly woman whose husband had died almost immediately before she started treatment. Of interest is that she emphasized how ill he had been during

his course of dialysis and that her situation was completely different from his. The other woman had Type I diabetes leading to ESRD and was undergoing hemodialysis; her husband had received a successful renal transplant several years previous to her need for treatment. She also described the circumstances of their illnesses as quite different.

Another woman also related a unique experience of family membership and dialysis experience. Her daughter had been receiving hemodialysis for some time before she initiated treatment. She indicated that her daughter had been especially helpful in telling her that it was not a bad experience, apparently intentionally describing it in positive terms.

Several patients whose family members (often parents) had been on dialysis and who were already dead described their experience of having to initiate dialysis as inevitable; they expressed a sense of resignation as they talked about their experience and their understanding of it. They also reported delaying the initiation of treatment as long as possible. One man (whose brother had been on dialysis and died following transplantation) described this delay as going into a "stall mode."

Perhaps the most poignant story of a personal experience from one of these patients was reported by a middle-aged black woman. While knowing of the existence of her renal failure for several years, she refused to initiate treatment until she was acutely ill with complications of pulmonary edema, congestive heart failure, severe peripheral edema. She recalled her and her family's experience with her sister's ESRD and hemodialysis treatment approximately 15 years before.

Of critical importance in her story the fact that sister had gone blind after starting hemodialysis; in addition, she died during a hemodialysis treatment after promising her nieces and nephew (this

patient's young children) that she would return from her treatment and take them to the park. This patient's children begged their mother not to undergo dialysis. Although they are now adults, they believed that their mother would suffer a similar death. In addition, this patient feared becoming blind like her sister had and being unable to continue her needlework hobbies. Apparently, she had not confided these fears and those of her children to her primary physician. Because no one, including her physician, was aware of her personal experiences, these fears seemed to be nearly overwhelming for her and apparently delayed her timely initiation of treatment. Other patients shared similar stories about personal experiences although none were quite as dramatic as this one.

Influences on Decision-Making

The patient's decision-making about and choice of ESRD treatment was measured through several of the questions asked in the interview process. Patients were generally not very specific in describing their decision-making process about treatment. Keeping in mind that patients in this sample have very different time frames in regard to both learning about their renal failure and need for treatment as well as making a decision about or choice of treatment, the questions asked in this interview sometimes differed slightly to reflect the patient's actual experience. Responses to this series of questions were incomplete. In addition, response rates varied from question to question.

This researcher also attempted to identify who might influence the patient's decision-making about treatment. In addition, it was important to identify whether this outside influence was or was not acceptable to the patient. Discussion regarding choice of treatment as it was perceived

by the patient showed that it was similar for patients who had or had not anticipated its occurrence.

Because 94 patients interviewed presumably had the opportunity to be informed and make decisions about ESRD treatment, these patients were asked about recommendations which might have been made regarding their treatment. In response to the question about whether their physician had made a recommendation for a specific treatment modality, 42 patients reported that the physician had made such a recommendation while 37 said that their physician had not done so. A more specific question was also asked to determine whether the physician had made a recommendation for initial (vs long-term) treatment modality. Of 70 patients who responded to this question, 51 indicated that their physicians made such a recommendation while 19 did not believe that such a recommendation had been made.

All patients who reported not knowing about their renal failure until time of initiation of treatment were receiving treatment via hemodialysis. They had all initiated treatment via hemodialysis; only one patient was imminently changing her treatment modality to peritoneal dialysis. With that exception, none of these patients reported that they were offered a choice of treatment modality during their hospital stay and at the initiation of their treatment in the hospital.

Influence about decision-making was measured via a series of questions related to whether it was recognized by the patient, who was responsible for influence, and whether this influence was acceptable. More patients (65%) who initiated treatment abruptly (without prior knowledge) reported that they had been influenced about treatment decisions than those who had known about their renal disease and need for

treatment. Almost half (49%) of them reported that influence had occurred.

The source of influence is also important to understanding the patient's decision-making process. Physician influence was most frequently reported. Of the 72 patients who identified the influential person in their decision-making, 37 of them reported that it was the physician. Twenty-two (22) patients reported influence by family. A summary of these responses is included in the following table.

Table 11

Decision-Making and Choice of Treatment

	#	%
Did You Discuss Choice of Treatment with Anyone? (n = 110)		
Yes	56	(51%)
No	54	(49%)
Did you Believe You Had Treatment Choice? (n = 100)		
Yes	54	(54%)
No	46	(46%)
Did Anyone Influence Your Decision? (n = 133)		
Yes	73	(55%)
No	60	(45%)
Who Influenced? (n = 72)		
Family	22	(31%)
MD	37	(51%)
Other	14	(20%)
Was Influence OK? (n = 68)		
Yes	60	(88%)
No	8	(12%)

Patients were generally not very specific in describing their decision-making process about treatment. However, several patients reported some revealing aspects of their decisions about treatment.

One young man who had known of his renal disease for several years and whose occupation was as a computer programmer brought to the interview appointment an actual copy of his decision-making matrix in which he used a numerical weighting system for the variables that he identified as significant to his ESRD treatment. He noted that there were other factors that he would have included if he had been aware of them. His decision-making was limited to a choice between hemodialysis and peritoneal as treatment options because his physicians recommended becoming stabilized on dialysis before considering transplantation as a treatment option. In addition, his understanding and decisions about treatment led him to insist on the placement of both vascular and peritoneal dialysis accesses during one surgical procedure to eliminate the need for an additional one. He was aware of the highly unusual nature of this surgical approach but found it perfectly "rational."

Another special story was reported by a young woman whose renal failure was caused by Type I Diabetes Mellitus. She had been fully employed as a registered nurse but indicated that her knowledge and understanding of chronic renal failure was minimal; she could not recall that this area had been covered in her nursing school curriculum. She did use her professional access to a medical library to gather information. In addition, she reported that her decisions regarding ESRD treatment were done as a group process in a family meeting; she reported this was a usual process in her family. As this patient discussed her decision-making and initiation of ESRD treatment, another family member joined the interview process with the consent of the patient. This family member was quite animated about a special aspect of the treatment process. She related that health professionals gave information and made plans for treatment

with this young patient's father rather than with the patient or other directly involved family members. They attributed this communication route to male dominance of father and physician; however, they reported that they confronted this problem and changed the communication process to include the patient and other involved family.

While the above table reflects the human aspects of influence on the patient's decision-making, it is important to note that many patients in both groups reported that it was their circumstance which served as the greatest influence. Many patients reported that they felt they had "no choice" about dialysis treatment. In fact, 14 patients who had prior knowledge of their renal disease reported that they felt they had no choice or alternative but to undergo "dialysis;" all of these patients were undergoing hemodialysis. One patient summed up their situation by saying "if you're sick, you take the necessary steps to put it in remission."

The influence of physicians as reported by patients is one of the strongest factors in their decision-making process. Fifteen (15) patients who knew about their renal failure reported that the physician "knows best," is the "expert," and that they trusted his "judgement." Fourteen (14) patients who began treatment emergently reported similar physician influence; these patients made the following comments about their experience: "just going along with what doctors told me; I had full trust in the doctors; doctor made all the decisions--I trusted him--I thought I was in good hands;" " doctors made choice about treatment--they decided what I needed--I didn't have anything to say about it;" "I do everything the doctor tells me to do;" "leave it up to the doctor--he knows more than I do in a situation like this;" "I leave my welfare in the hands of the doctor."

One patient reported this influence somewhat differently when he said that his doctor would not let him go to the hospital unless he agreed to go on dialysis. He recalled that the doctor told him to either go home or go on dialysis when he had presented in the emergency room with symptoms of renal failure. He was told that if he went home, they would bring him back "in a box" the next time. While these statements sound rather dramatic and threatening, this patient is the only one of the entire sample of 150 who stated that he was denying his renal failure. He had refused to initiate dialysis when it had previously been suggested because he felt that his medical condition could continue to be controlled with medication. This belief had been reinforced by improvement with medications that had been achieved during previous hospitalizations. In addition, his wife did not want him to initiate dialysis although he did not reveal her reasons.

Family influence was reported much more dramatically by those patients who needed treatment emergently and had no prior knowledge of their renal disease than those who did. Some examples of this influence are expressed by patients in a number of ways. For example, an 18 year old reported that his "mom told me I should do it."

The influence of family was especially strong for the elderly patients whose offspring appeared to be the actual decision-makers; these patients explained their situation as "my family saw a movie; I did whatever they wanted to do; my daughter knows the score--she takes care of me; my daughter makes all the decisions; my granddaughter--she says it isn't as bad with me; it was a family decision to do dialysis; did what my daughters wanted; my wife, mother-in-law wanted me to do it." These statements were all made by persons who were identified as competent to give their own consent for treatment.

Emergent Decision-Making

In an attempt to measure whether the emergent nature of initiating treatment for those patients who did not know of their existing renal disease/failure affected decision-making about treatment, patients were asked specific questions about their experience. These questions were asked to those 56 patients who indicated that they had no prior knowledge of their renal failure.

It is clear that opportunity to make decisions did not seem to be available to the majority of the patients who responded to this question. In addition, decision-making about treatment did not seem to be the most important consideration. In fact, these respondents emphasized that their decision-making primarily focused on life and death. A summary of these responses appear in Table 12.

Table 12

Emergent Decision-Making

	#	%
Opportunity to Make Treatment Decisions (n = 39)		
Yes	17	(44%)
No	22	(56%)
Most Important Decision to Make (n = 39)		
Life or Death	36	(84%)
Treatment Type	7	(16%)

As reported above, many of these patients did not feel that they made any treatment decisions. They attributed the decision-making about treatment to the situation, the physician, and/or their family. It is of interest that all but one of these patients continued the treatment modality (hemodialysis) that was initiated on this emergent basis.

Satisfaction with Treatment

A group of questions were asked to determine whether the patients were satisfied with the treatment chosen, and which they were undergoing at the time of interview, or whether they would prefer a different treatment modality. A number of patients were unable to answer these questions because they had not participated in a decision-making process about treatment modality; a number of patients who apparently had not been informed of other treatment modalities could not appropriately answer these questions because they were not aware that any other treatment modalities were available. Several patients commented that they were not satisfied with the treatment they were receiving even though they knew of no other options; they wanted their kidneys to function again.

The questions regarding satisfaction with treatment and preference for another treatment modality were asked of all 150 subjects. While many patients were unable to answer these questions, there are a number of patients who are not satisfied with their current treatment. Renal transplantation is the most preferred type of treatment for those few patients who were aware of alternatives.

All of the 47 patients responding to the question regarding treatment satisfaction were patients who had prior knowledge of their renal disease and had been able to gather information about treatment modalities. Thus, this group includes all but one of the patients who were undergoing peritoneal dialysis and all of the patients in this sample who had received a kidney transplant at the time of interview (see Table 13).

Table 13

Satisfaction with Decision and Treatment

MODALITY	#	%
Able to Receive Treatment of Choice (n = 47)		
Yes	46	(98%)
No	1	(2%)
Satisfied with Treatment Receiving (n = 83)		
Yes	56	(84%)
No	27	(16%)
Other Treatment Preferred (n = 28)		
Hemodialysis	0	(0%)
Peritoneal Dialysis	6	(21%)
Transplant	22	(79%)

No Treatment as an Option

The final questions in the interview measured another aspect of decision-making indirectly related to treatment modality. In an attempt to more completely understand the patient's decision-making process, it was important to determine whether the patients understood their right not to undergo treatment and the result of such a decision.

Patients made several interesting comments about the outcome of not undergoing treatment. Of the majority who knew they would die without treatment, they frequently stated that they were not ready to die yet. The majority of those patients who started treatment emergently and thought they would die without the treatment seemed to come to that conclusion because of how sick they felt.

Very few patients stated that loss of kidney function was fatal but rather, they judged this disease as fatal because of their symptoms and complications such as shortness of breath and associated chest pain.

Eight (8) patients stated that they considered not initiating treatment as being an act of suicide. One patient related this belief to his recent conversion to Catholicism. The other patients responding in this way had not indicated that their religious beliefs influenced their health care decisions. One patient reported that this was the terminology (committing suicide) that was used by a nurse when she discussed with him the outcome of not undergoing treatment.

In addition, two patients who had signed a durable power of attorney stating that they did not wish to be placed on life support systems expressed confusion about the initiation of dialysis while not mentally cognizant; both considered hemodialysis as constituting a life support system. Finally, two patients very clearly stated that, even though they had started dialysis, they still were not sure that they wanted to continue it. They also were able to state that they would die if they discontinued treatment. The compilation of responses to these questions are reported in Table 14.

It is also important to note that those patients who started ESRD treatment on an emergent basis and without prior awareness of their kidney disease were less likely to not consider undergoing treatment. Only 27% of the patients (n = 47) responding to this question indicated that they had considered not receiving this treatment while 38 of 91 (42%) of patients who were aware of their renal disease had considered not undergoing treatment. The meaningfulness of this difference is unclear but warrants further study.

While patients were correct in understanding the outcome of their renal failure without ESRD treatment, their responses to this question were usually expressed in a tentative or questioning manner. The lack of

Table 14

No Treatment Decision-Making

	#	%
Ever Consider Not Undergoing Treatment (n = 138)		
Yes	51	(37%)
No	87	(63%)
When Did You Consider (n = 49)		
Before Treatment	16	(33%)
As Began Treatment	11	(22%)
Before Leaving Hospital	10	(20%)
Other	12	(24%)
Why Change of Mind (n = 49)		
Family Wishes	21	(43%)
MD Advice/Order	1	(02%)
Physical Status	10	(20%)
Other	17	(35%)
No Treatment - Result (n = 128)		
Death	114	(89%)
Become More Ill	11	(09%)
Other	3	(02%)
Anyone Tell You Result (n = 33)		
Yes	16	(48%)
No	17	(52%)
Who Told You (n = 16)		
MD	13	(81%)
Nurse	1	(06%)
Other	2	(13%)

discussion or explanation of this outcome with health care practitioners in a value-neutral fashion appears evident from these patient responses.

Data Analysis Based on Patient Perception of Treatment Choice

Although attempts were made to identify significant differences, particularly based on sociodemographic variables, in regard to whether patients knew or did not know of their renal disease, these analyses were essentially nonrevealing of any differences between such groups.

In an attempt to determine whether there were any differences in the decision-making process for the 150 patients in this sample, the question of choice of treatment was used as a dependent variable to determine if any sociodemographic variables influenced the patient's perception of choice of treatment modality.

Group A is composed of 54 patients who stated that they felt they had a choice regarding treatment in response to a specific question asked in the structured interview. Group B included 46 patients who answered that they felt they had no choice regarding treatment in response to that specific question. The total number of patients included in this analysis is 100; 50 patients did not respond to this specific question during the course of their interviews.

Using the Crunch Statistical Program, data analysis was performed on selected independent variables to determine if there are any identifiable significant differences between those patients who felt they had a choice and those who felt they did not. Depending on the type of variable entered, Chi Square or Kendall's tau b testing was performed for statistical significance.

This analysis revealed that the independent sociodemographic variables of age, marital status, level of education, employment status, and medical insurance coverage provided statistically significant results. These results are reported in Table 15.

The variables of patient sex, ethnicity, income, closest family member, living circumstances, family accompaniment to MD, feeling of need for secrecy, and prior personal experience with ESRD were not significant to the patient's perception that they did or did not have a choice of ESRD treatment.

Table 15

Sociodemographic Variables and Choice of Treatment

VARIABLE	P VALUE
Age	0.0001+
Marital Status	0.0846*
Educational Level	0.0006+
Employment Status	0.0182*
Medical Insurance	0.0060*

+Kendall's tau b analysis
*Chi square analysis

Variables related to the patient's medical condition and health care including cause of renal failure, patient awareness of disease, physician care, nephrologist care, referral to other health care professionals for information, discussion with other patients, hospitalization at time of treatment, or consideration of not receiving treatment were not significant to the patient's perception of choice.

Two additional variables related to the patient's health care delivery system were analyzed to determine their influence on the patient's perception of whether they did or did not have a choice of treatment. Of the variables tested, only two were statistically significant. The receipt of written/video information about ESRD treatment by the patient was statistically significant (P=0.0088) by Chi square analysis. The influence of others on the patient's decision-making was also statistically significant (P= 0.0149) by Chi square analysis. The primary source of such influence was reported by patients as being their physician with family members also exerting some influence.

In summary, the sociodemographic variables of age, marital status, education, employment, and type of medical insurance coverage are all significant to the patient's perception that he/she made a choice about treatment modality for ESRD.

Patients between ages 26 and 55 perceived greater choice than patients between ages 18 and 25 and over age 55 (to age 85). Patients who were single or divorced felt they had greater choice than those who were married, separated, or widowed.

Patients who had Medicare and private insurance or Medi-Cal as secondary coverage did not feel they had a choice of treatment. Level of education (ordinal scale from none to postgraduate education) indicated that patients with less than a high school education felt that they had no choice while those who had attended or graduated from college or a technical school following high school felt they had a choice of treatment. Employment status identified that retired people felt they had no choice of treatment.

Two other variables were significant to the patient's perception of choice. Patients who had received written or video information about treatment felt that they had a choice of treatment while those who had not felt they had no choice. Finally, patients who felt they had been influenced by someone else regarding their treatment felt they had no choice of treatment.

To determine the impact or influence of these independent variables on the patient's perception of choice about treatment, a logistic regression was performed. The sociodemographic variables of age, sex, educational level, income level, marital status, ethnicity, and employment status as well as the two health care variables of medical insurance

status and whether the patient was seeing a physician were used as independent variables in this analysis. The dependent variable remained whether the patient believed he/she had a treatment choice. A total sample size of 93 patients was used for this analysis; 44 patients had responded that they had no choice while 49 patients believed they had a choice.

This logistic regression was performed using the Crunch Statistical Program. The dependent variable is a dichotomous variable of choice/no choice. The independent variables were both quantitative dichotomous and categorical; if the variables were categorical, they were dummy coded for purposes of analysis.

Results of this logistic regression analysis show that the variables of age, income, and employment status significantly predict the perception of patient choice about treatment. Statistical results of this analysis are shown in Table 16.

Table 16

Predictors of Patient Choice of Treatment

VARIABLE	P VALUE	95% CONFIDENCE LEVEL
Age	0.0006	0.05 - 0.45
Income	0.0021	1.25 - 2.71
Currently Working	0.0041	0.00 - 0.19
Short-Term Disability	0.0208	0.00 - 0.19

Overall Percent Correct = 81.7%

While the results of this regression analysis are interesting and appear to be statistically significant, the sample size is relatively small due to multiple nonresponses to specific questions in the interview

CHAPTER V

CONCLUSION

Meaning of Findings

This exploratory study provides an initial report of the ESRD patients' access to information and treatment and how they perceive their role in making decisions about treatment. The most important finding is that even patients who are aware of their impending need for ESRD treatment do not have universal access to information about treatment, do not have available to them a uniform mechanism for obtaining information and education about treatment, and are not well informed about their choices of treatment modality. For patients who are not aware of their renal disease and the possible development of renal failure requiring replacement therapy, access to information about various treatment modalities and the opportunity to make decisions about treatment is even more restricted and may even be nonexistent.

It is most significant that the group of subjects who knew in advance of their renal disease and those who did not know were remarkably similar by analysis of all such independent variables except for knowing the cause of their renal failure and the time before needing treatment. The variables of age, sex, marital status, and ethnicity apparently have no impact on awareness of impending renal failure and need for treatment in this convenience sample of 150 subjects.

Religious affiliation and its importance was strong in this sample of subjects. The relationship of this variable remains unclear to the patient's decision-making process, however. While 8 subjects reported

that not undergoing treatment would have constituted an act of suicide, not all of those subjects related the act of suicide to religious beliefs. Rather, it appears that this is more of a life philosophy or perhaps even a philosophy about the use of modern medical care--use everything that is available to continue life. Two (2) patients did specifically report that not undergoing treatment was suicide within the context of the Catholic religion and thus was forbidden. Within the context of life-sustaining treatment, this may well be an invalid interpretation on the part of these patient--they did not note that they had discussed their decision-making about treatment with a religious advisor.

This study, of course, did not measure the responses of patients who chose not to undergo treatment (no study has reported on such a group and the significance of religious belief to such a decision). It is significant that the majority of patients were willing to undergo life-sustaining treatment but a few clearly were still not certain (at the time of interview) that they wished to continue treatment. In addition, it is unclear how "living wills" or durable power of attorney documents can be used to interpret or express the patient's wish regarding the life-sustaining technology of ESRD treatment. In addition, health care professionals seem to minimize the life-sustaining nature of ESRD treatment (particularly dialysis treatment) by defining it as a "chronic" treatment.

Patients are also apparently not advised by their physicians or other health care professionals in a value-neutral way about the outcome of ESRD without treatment. While the majority of subjects did indicate that they would die without treatment, this fact was rarely validated by the physician or any other health care professional prior to the

initiation of treatment. Although no specific question in this study was included to determine whether patients had been advised that they do not have to undergo treatment (that they can refuse any treatment), the absence of direct discussion about the outcome of renal failure suggests that this option is not directly discussed.

Neither income nor educational level appeared to have any significance in regard to subject awareness of their renal failure; employment status also did not impact seem to have any significance in regard to patient awareness of their renal failure.

Contrary to other research previously reviewed in this report, health care coverage by private plans, Medi-Cal, and or/Medicare did not seem to impact on access to medical care and ESRD treatment. The majority of subjects interviewed for this study had some form of health care insurance that had allowed access to prior and ongoing medical care. It is somewhat surprising that almost all patients (148/150) had some form of medical insurance in this sample. It is fairly clear that patients facing ESRD even without current health care coverage can receive emergent care. Health insurance status, however, seems to have no effect on whether or not patients know about their renal disease and need for treatment.

Access to physician care was readily available and utilized by patients in this study. Eighty (80) patients or 47% of the entire sample reported that they had been seeing a kidney specialist before undergoing treatment; this number includes 8 patients who reported that they did not know they had renal failure. Ninety-one (91) patients (60%) of the sample of 150 reported that they were seeing a physician regularly although many patients were unclear about their physician's specialty. Some patients seeing kidney specialists (nephrologists) did not identify them as such a

specialist but rather as their "regular" doctor. Only two patients reported that they were not seeing a physician on a regular basis because of lack of health insurance; both of these subjects were young adult males who had apparently exhibited no symptoms of renal failure until they reached end-stage disease.

The advanced mean age and coverage by Medicare for the older patients most likely enhanced their access to health care. For patients who had been declared as disabled (particularly patients with Type I Diabetes), their Social Security disability status provided them with MediCal or Medicare coverage.

A more subtle form of access limitation to patients preventing them from obtaining information and making decisions about treatment prior to its initiation does appear to be operant in this sample. Even though many of the subjects who reported that they did not know of their renal failure had primary diseases which they could identify (e.g., hypertension, diabetes) and which have a high association with chronic renal failure, they were not being seen by a kidney specialist; however, they were under the regular care of a physician. The nature of these illnesses include the progressive deterioration of renal function which is measured via routine blood studies; thus, it must be assumed that the primary physician is aware of the progressive renal failure of his/her patient. Some of these patients reported that they had seen a kidney specialist on one occasion (referred by their primary physician) but were not sure why or did not understand the significance of the referral. That nephrologist was again contacted by the patient's primary physician when he/she required initiation of ESRD treatment. This type of gate-keeping by the primary physician appears to limit the patient's access to specific

information about ESRD treatment that could/should be provided by a nephrologist.

This limitation of access to information is validated in the responses of the subjects who knew about their renal failure by their responses to the questions about receiving written information, talking to other health care professionals, having the opportunity to visit dialysis facilities, and talking with other patients about treatment; these services were not universally available to them. The patients who were unaware of their renal disease had no opportunity to obtain any education or information about ESRD treatment. A minimal amount of information was provided in the hospital setting but only after ESRD treatment had been initiated. This lack of education and information is further reflected by the fact that the majority of subjects who did not know about their renal failure were not informed of their treatment modality options.

A similar (and perhaps more distressing) finding is that only 53% of the subjects who knew about their renal failure were informed of the different treatments available to them for their ESRD. Of the subjects who were advised of their options, only 39% were advised of all those currently available (hemodialysis, peritoneal dialysis, renal transplantation). These findings suggest that patients are not being completely informed of their treatment options although it is unclear what factor(s) create this situation.

Few patients also have access to other professionals to assist in their obtaining information about treatment modalities; in addition, the subjects who did report that they talked to nurses or social workers and/or visited a dialysis unit frequently did so without formal arrangements or referral. These subjects reported that they were told

they could "drop by" the dialysis unit; they then spoke to whomever was available at the time; others reported that they "peeked into" the facility particularly if it was located adjacent to their physician's office. However, even when the outpatient dialysis facility was next to or across the parking lot from their doctor's offices, patients apparently did not generally feel comfortable about visiting the facility; formal arrangements for visiting were more unusual than usual. One patient reported going to the unit the day before treatment began to assure that he could find it at the time of his scheduled appointment.

These kinds of activities hardly provide adequate education and information for the subject although they are recognized as positive experiences by the patient. While nephrology nurses and other health professionals believe that patients should be educated and informed about their treatment, they have not organized formal programs to provide education on a universal basis.

Patients in four of the interview settings did report attending a class or speaking with other health care professionals and/or patients about ESRD treatment. It is significant that these facilities are hospital-based teaching facilities (one is a county facility, one a VA facility, and two are university based medical centers).

The physicians seeing the pre-ESRD patient are full-time staff members who do not maintain outside private practices; all other members of the ESRD health care team are in the same facility (in close geographic and perhaps, collegial, proximity). This difference in patient access to information between health delivery settings (private practice and institutional) also suggests that gate-keeping in the private practice setting prevents patients from accessing information about ESRD treatment.

Furthermore, it is clear that the nursing organizations in these facilities have defined the education of potential ESRD patients as a part of their professional obligation and responsibility. However, such educational programs were not identified in free-standing dialysis facilities. In addition, the interaction of patients with hemodialysis nurses in the hospital who provided acute treatment provided very little education or information to patients. For reasons that are unclear but probably are created by structural and role definitions in the ESRD setting, dialysis nurses provide very little education and information to patients before they initiate ESRD treatment.

In addition, there appears to be little discussion about ESRD treatment by private-practice physicians (including nephrologists) providing care to the potential ESRD patient. No specific appointment time is devoted to discussion of treatment options and family members are not necessarily encouraged or specifically included in such discussions. While patients are sometimes provided with written educational materials, this is fairly unusual even though all of these materials are free to physicians and their patients.

Do physicians find themselves ill-prepared to discuss ESRD treatment with patients before it must be initiated or do they feel that such information is simply not necessary for the patient? From the explanations about dialysis that patients said they received from their physicians, this researcher was impressed by the rather low-key attitude of inevitability that seemed to be portrayed by the physician in talking about treatment. In addition, the almost universal use of the term "dialysis" (apparently meaning only hemodialysis) provided the patient with no information about other treatment modalities.

Physicians seem to routinely recommend an ESRD treatment modality for patients as either an initial modality or as an ongoing one. Because patients are poorly informed about the different modalities available, because they trust their physician's judgement, and because they acknowledge the power of the physician's influence on their decisions, it is not surprising that the physician's recommendation for undertaking a treatment modality is not questioned by the patient who has little knowledge or is not empowered to ask questions about alternatives.

Satisfaction with treatment as expressed by patients shows that patients who have presumably had time to consider their treatment are more satisfied than are those who had to make emergent decisions. In addition, the majority of those who would prefer another type of treatment would prefer to receive a kidney transplant, a treatment which would free them from the chronicity of dialysis treatments.

Of those patients who had known of their renal failure and who expressed a preference for a transplant, most had not yet been evaluated for this treatment modality. ESRD treatment planning obviously favored the initiation of treatment with hemodialysis.

As patients provided the information and explanations that they had understood about treatment modalities, it also appears that some physicians are poor educators who find it difficult to explain treatment modalities in lay terms and in a fashion that includes an understanding of a patient's unique life situation or preferences. In particular, the generic term "dialysis" was repeatedly used by patients (as learned from their physicians) and was understood as synonymous with hemodialysis; thus, it implicitly excluded the definition of the modality of peritoneal dialysis. It is unclear whether this is an intentional or unintentional bias about treatment modality on the part of the physician.

The experience of patients who have had family members and friends on dialysis should not be underestimated. Especially important is the fact that most of these family members or friends are already dead; it is unclear from this research what impact this situation has on the patient facing ESRD and its treatment although individual situations reported by patients strongly suggests the psychological importance of this aspect to the patient's view and understanding of ESRD, its treatment, and outcome.

The second analysis performed on this sample of 150 patients when using the dependent variable of whether or not they felt they had a choice about treatment more clearly revealed significant relationships with several independent variables. The demographic variables of age, marital status, educational level, and employment status all proved to be statistically significant to patient's perception that they had a choice about their ESRD treatment.

These demographic findings can be summarized by stating that older, less well educated, retired, married persons felt they had less choice about treatment than younger, more highly educated, single working people. In recalling that physicians and other health care professionals probably relate better to persons like them (similar sociodemographics), these findings are not at all surprising. It is not unlikely that physicians continue to believe that younger working patients are more likely to undertake or benefit from peritoneal dialysis or a kidney transplant. However, it is also likely that younger patients are more aggressive in learning about their treatment options while older patients are more passive in their patient role and accede to the physician's recommendations without question.

Although the sample size becomes relatively small, the logistic regression analysis performed on this second data base as reported above further shows that the variables of age, income, and the patient's employment status are the strongest predictors of whether patients feel they have a choice about their ESRD treatment. The analysis supports the previous simple Chi-square analysis reported above. It verifies that patients who are younger, who are currently working or will likely return to work following their acute illness, and who have a higher income level are most likely to have a choice about their ESRD treatment.

In summary, it is clear from these data that the processes of patient education and decision-making which are integral to informed consent are not being achieved in the pre-ESRD setting even though there is an ample time opportunity for this to occur in an organized fashion. For patients who confront the diagnosis of ESRD emergently in the hospital, the continuation of hemodialysis treatment as initiated in the hospital was universally carried out for all patients in this sample even though it is feasible for patients to choose peritoneal dialysis as an ongoing treatment modality. Of course, renal transplantation could not be arranged emergently for this patient population.

Significance

The End Stage Renal Disease Program requires that all patients be informed of their treatment options prior to initiating therapy. This study suggests that the intent of this regulation to ensure that patients are making informed choices of treatment is not being achieved. The barriers to informed consent are multiple but are slightly different and more subtle than such barriers to treatment which have been identified elsewhere in the literature.

Based on comparisons with the ESRD patient population of northern California as well as data describing the U. S. ESRD Medicare population, the 150 patients interviewed in this convenience sample appear to be representative of the ESRD population. Thus, the information provided by these patients can also be considered representative of the larger ESRD population.

The incidence of patients initiating ESRD treatment for chronic renal failure without prior knowledge of any renal disease is a significant finding in this study. Fifty-six (56) patients (37%) in this sample of 150 denied knowing of the presence of their renal disease until they initiated treatment. Given that most of these patients were receiving regular medical care and assessment, it is difficult to believe that there was no biochemical evidence of deteriorating renal function prior to these patients' hospital emergency room presentation in a uremic state. The reasons for this lack of knowledge or understanding by patients about their medical condition may well be multifactorial and requires further investigation. The gate-keeping nature of nonreferral of these patients to a nephrologist before they require ESRD treatment also needs careful study and analysis.

The finding that physicians (both primary physicians and nephrologists) apparently do not discuss treatment options with their patients in a formal manner is significant to the patient's decision-making process and ability to give informed consent for treatment. The repeated use of the term "dialysis" as patients reported what physicians told them clearly identifies that their physicians do not introduce or explain the various treatment modalities, how they are performed, and their outcomes.

The predominance of patients undergoing hemodialysis as their first treatment modality also suggests that physicians undertake a decision-making process for patients about their treatment modality without considering that patients' preferences or values are an integral part of the process. In fact, those physicians who do not inform patients about other treatments are also practicing a form of gate-keeping although the reasons for that are unclear from this research.

Possible explanations for this lack of information may be attributed to the physician's unfamiliarity with all treatment modalities, unavailability of all modalities in the facilities in which they practice, financial disincentives for referral of patients to other practitioners for treatment, avoidance of difficult discussions with patients about ESRD treatment, and physician bias about the efficacy and success of treatment.

It also seems clear that physicians consider ESRD treatment as a usual and customary treatment rather than as an extraordinary one. The value and classification of this treatment as life-sustaining appears to be minimized. Many subjects reported it as an inevitable treatment about which they had no choice. It is interesting that one patient expressed concern about the initiation of treatment for him in the hospital even though he had signed a document refusing all life-sustaining treatment; he recognized that dialysis was a life-sustaining treatment.

On the other hand, two family members described having to fight for treatment of their next-of-kin; one patient was a quite elderly gentleman, the other was a severely mentally retarded young man (who had previously received full treatment for Hodgkin's disease); these families were unclear as to the reason for recommendation against treatment.

The minimal use of other health care team members (nurses and social workers) in pre-ESRD patient information and education also may limit the patient's decision-making and informed consent process. With educational materials readily available at no cost to the patient or health care provider, it is especially significant that few patients have received such materials before initiating treatment; however, it is also necessary to recognize that these materials may not be read by patients or that they may be unable to read them. The reliance on providing written materials to achieve patient information and education is thus inappro-priate. Educational materials do, of course, need to be individualized to the needs of each patient.

Limitations and/or Alternate Explanations

As previously noted, a small number of patients whom this researcher saw in consultation about their choices for ESRD treatment were excluded from this study. While the number of patients excluded for this reason was small, their exclusion should be noted. On the other hand, their inclusion would also have altered the data because this work is relatively unique in the northern California area.

Because this research relied on the consent of nephrologists for interview of their patients, the convenience sample is limited to those patients whose nephrologists agreed to participate. It is totally unclear why physicians did or did not allow their patients to be interviewed. It is unclear how this participation/nonparticipation biased the results of this study. It is, however, difficult to verify that the patients who were excluded from this study were discernibly different from those who participated in the interviews.

The interview of subjects for this study provides a potential for biased information as reported by the patient. However, since it was the intent of this study to document what these subjects understood about treatment and how they made decisions based on their understanding, this bias cannot be considered as critical to the findings; actually, it should strengthen the importance of the findings. If physicians and other health care providers provided patients with more complete information about treatment than was reported by the patients in this sample, it was apparently not understood well enough by these patients to be retained and used in their decision-making process. Thus, the entire health care team must assume responsibility for adequate patient education and understanding about their disease and its treatment.

The role of denial has often been cited as the reason that ESRD patients do not seem to know much about their disease or its treatment. While two subjects in this study specifically acknowledged their avoidance/ delaying of treatment, they also indicated that additional information would have been useful. The use of denial as an excuse not to offer or provide patients with education and information about treatment may occur when physicians or other health care professionals find it difficult to do so.

The patient may indeed use the concept of minimal consequence in interpreting the information given to him/her by the health professional; because this research did not observe patient/provider interactions to document the information provided, it is impossible to determine how much denial or minimal consequence framing was operant for the patient in considering treatment. Because the interactions with the health provider were ongoing (constituting a relationship), these barriers to understanding could have been minimized by continued discussion.

The role of physicians in not wishing to discuss "bad news" (e.g., the need for dialysis in the patient's life) is also unmeasured in this study. The lack of discussion about not undergoing treatment or not validating patient outcome without treatment that was noted in this study does suggest, however, that physicians may be avoiding such difficult discussions.

Because families were not generally included in the interview process, this research reflects that many patients did not remember much of what occurred, especially those patients who initiated treatment on an acute/emergent basis without previous knowledge of their condition. The role of families in the decision-making process may well have been undervalued by many of the subjects interviewed. The information that family members received from health care providers (especially physicians) may have been more complete than that reflected by the patient; in addition, the family members' decision-making process for the sick patient may have been greater than reflected by the patient.

Implications for Nursing

This study identified that only 17 of the 150 patients spoke with a nurse before initiating treatment. While the content of these interviews was not documented, it is unlikely that these sessions with the nurse were primary educational meeting about treatment modalities.

Based on this researcher's clinical experience and comments from some of these subjects, these interactions more likely focused on an introduction to the hemodialysis unit and the practical aspects of receiving treatment. As several subjects indicated that a visit to the facility was helpful because the staff were so "nice," it is likely that these were brief introductory sessions to the facility.

Subjects who had not known about their treatment did receive information from dialysis nurses while they were in the hospital. Patients reported that these interactions primarily focused on an explanation of the hemodialysis treatment that they were undergoing at the time. It is unlikely that these interactions contributed to the patient's decision-making process in a significant way, however.

In the dialysis facility, the primary provider of care is the Registered Nurse with the assistance of Licensed Vocational Nurses and dialysis technicians. As the patient initiates treatment, the RN is responsible for obtaining informed consent for treatment and for completion of the Life Care Plan which is intended to verify that the patient has been informed of his/her treatment options. The nurse's function in obtaining these consents assumes that he/she is verifying that the patient is aware of and understands his/her treatment options.

Based on the research reported here, it is unlikely that this goal has been achieved as the patient enters the dialysis facility. When a patient explains hemodialysis and peritoneal dialysis only by the location of the access ("a tube in the arm or a tube in the stomach" according to one patient), it seems obvious that the patient has not been fully informed of his/her treatment options.

After the patient has initiated hemodialysis, he/she is readily available to the nurse for continued education and information about other treatment modalities; such education may result in the patient transferring to another modality that is more acceptable to him or her. However, this process does not satisfy the intent of the ESRD Regulations.

It is, therefore, essential that ESRD nurses design and implement programs which will assure access to the pre-ESRD patient for appropriate

information and education about treatment. Such a program requires the use of an expert nurse who is familiar with discussion of all treatment modalities and who can present each of them in an unbiased fashion. The nurse should also be able to understand the variables that impact on patient decision-making either to maximize their appropriate utilization by the patient or to teach the patient how to make a decision about treatment.

Such a program is entirely within the context of nursing's scope of practice; the nurse serves as patient educator and advocate for assuring that the patient is fully informed of his/her treatment options and that the patient's preference can be obtained. The organization of nephrology nursing should include this role and activity to fully ensure informed patients undergoing treatment as successfully as possible.

Future Research

This study raises a number of questions that require further investigation if we are to understand the decision-making process that patients undertake about their ESRD treatment. This research has begun to answer questions about direct patient care and health policy issues relative to the ESRD patient; as this information was obtained, other questions are raised.

While this study interviewed 150 patients in a relatively large and diverse geographic area, it is necessary to determine whether these findings reflect general health care practices and patient responses in regard to ESRD care. Thus, continued study of this decision-making process in a larger population and in an expanded geographic area is necessary to either refute or verify the initial findings of this exploratory study.

Because the belief still exists among some health care professionals that denial of their illness and the effects of the uremic state on the ESRD patients' cognitive functions prevent them from being able to process information and make appropriate decisions about their health care and treatment, it seems essential to test these beliefs. Replication of the early work which promulgated this belief is really essential to determine this aspect of the ESRD patient's behavior and well-being and whether it affects their decision-making. Similarly, studies of cognitive function in the pre-ESRD treatment renal patient are needed to document whether they are generally neurologically able to make decisions about their care.

Because this study gathered data retrospectively, the results are subject to their accurate recall and interpretation by the patients who were interviewed. More accurate analysis of patient decision-making about treatment could be performed via a longitudinal study of pre-ESRD patients as they go through this process.

The role of significant others such as family and friends needs further study to determine its influence on patient decision-making. The interview of family members to validate or explain their understanding and involvement in the patient's decision-making process needs to be measured. In addition, more data needs to be collected about the patient's prior or current personal experiences with their general health care delivery and particularly with ESRD treatment to determine its effect on their decision-making about treatment.

To determine whether there are communication and interpretation gaps between physicians and their patients which influence what the patient understands about ESRD treatment, a study designed to observe and analyze these interactions would provide valuable information about this aspect of

patient education and decision-making. Theoretical frameworks of decision-framing or minimal consequence could be used to guide and analyze this data.

The interactions of other health care professionals with the pre-ESRD patient and their influence on patient decision-making also require further study to determine whether they play a significant role. An experimental design could also measure the specific interventions of various health care professionals and their effects on the patient's decision-making process about treatment. In particular, nephrology nurses need to identify their role in the patient's decision-making process through research and implementation of nursing activities.

This exploratory study also raises some major health policy questions about patient care and their decision-making. A major issue that needs further study in a larger group of patients and a more extensive geographic area is the issue of gate-keeping that has been identified in this research.

How frequently are patients not referred for specialized management of their renal disease and/or preparation for treatment in a timely fashion? How are these referral patterns determined and what effect does late referral have on patient decision-making about treatment, satisfaction with the treatment they receive, and the cost-effectiveness of that treatment? What is the effect of this apparent gate-keeping activity on patient acuity and need for hospital services as ESRD treatment is initiated?

Further study is also required to determine why such a large percentage of patients in this sample were unaware of their medical condition and the impending need for ESRD therapy. In a health care

system that places a very high value on patient information and education, this finding is particularly disturbing. Further study needs to determine who and what is responsible for this situation and how it should/could be corrected.

Finally, cost/benefit studies should be performed to determine the effect of patient education and appropriate decision-making on the cost of initiation of ESRD treatment. Are health care costs decreased for the patient who has been educated and well-informed about ESRD treatment vs. the patient who has received no information? Is the patient's choice of ESRD treatment modality affected by pre-treatment education and information which also has an effect on the cost of ESRD treatment? What is the cost/benefit of this aspect of patient decision-making about treatment modality? In addition, definitive study needs to be carried out to determine why patients do not receive earlier referral for renal transplantation in the course of their pre-ESRD management or whether such referral is based on other biases. The question needs to be answered of why there appears to be such a delay in referral to this treatment modality.

Another health policy issue relevant to patient decision-making about ESRD is the effect of the patient's age on the ability and willingness to make their own decisions about treatment rather than deferring to the physician as was found in this study. Are older or aged patients who require ESRD treatment capable of processing information and making decisions about their therapy when the health care system supports their doing so or does this population truly have a different approach toward participating in their own care that should be acknowledged by health care professionals? Is the bias found in this study toward greater

decision-making by younger, more well-educated, economically advantaged patients a result of physician or patient behavior? Can and should this situation be changed to allow or mandate greater participation by the apparently disenfranchised groups? Do they wish to be more empowered and involved in their health care decisions? These questions require study and analysis in regard to both the ESRD patient population as well as more generalized health care patient populations.

Finally, formal study is needed to analyze how ESRD patients perceive the granting of informed consent relative to their decision-making process and initiation of ESRD treatment. In regard to patients' informed consent, serious study needs to be performed to determine how patients understand the life-saving and life-support nature of this treatment. In addition, study needs to be performed to determine the decision-making process that this undertaken by or for those patients who do not undergo ESRD treatment.

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APPENDIX A

HCFA Form 2728

Evidence of End Stage Renal Disease

FORM APPROVED OMB NO 0938 0046

CHRONIC RENAL DISEASE MEDICAL EVIDENCE REPORT

NO MEDICARE BENEFITS MAY BE PAID UNLESS THIS FORM IS RECEIVED AS REQUIRED BY EXISTING LAW AND REGULATIONS (42 C F R 405 104) INDIVIDUALLY IDENTIFIABLE PATIENT INFORMATION WILL NOT BE DISCLOSED EXCEPT AS PROVIDED FOR IN THE PRIVACY ACT OF 1974 (5 U S C 5520 45 C F R PART 5a)

IDENTIFYING INFORMATION

1 PATIENT S NAME (LAST, FIRST, MIDDLE INITIAL)		2 PATIENT S OWN SOCIAL SECURITY NUMBER		
3 PATIENT S ADDRESS (STREET, CITY, ZIP)		4 PATIENT'S CLAIM NUMBER		
5 PHONE NO *	6 COUNTY OF RESIDENCE *	7 DATE OF BIRTH		
8 ADDRESS OF SOCIAL SECURITY OFFICE	9 PATIENT S SEX * ☐ a MALE ☐ b FEMALE	10 RACE * ☐ a AMERICAN INDIAN OR ALASKAN NATIVE ☐ b ASIAN OR PACIFIC ISLANDER ☐ c BLACK ☐ d WHITE ☐ e UNKNOWN		11 ETHNICITY* ☐ a HISPANIC ☐ b NON-HISPANIC

12 NAME, ADDRESS, AND PHONE NUMBER OF PHYSICIAN RESPONSIBLE FOR RENAL TREATMENT AT TIME OF CLAIM

13 PRIMARY DIAGNOSIS (CAUSE OF ESRD) **	14 SECONDARY DIAGNOSIS *

TREATMENT INFORMATION—DIALYSIS

TYPE OF DIALYSIS	DATE REGULAR DIALYSIS BEGAN	FREQUENCY SINCE REGULAR DIALYSIS BEGAN (TIMES PER WEEK)	HAS DIALYSIS ENDED?	IF ENDED, DATE OF LAST DIALYSIS
15a ☐ HEMODIALYSIS	15b	15c	15d ☐ YES ☐ NO	15e.
16a. ☐ PERITONEAL	16b	16c	16d ☐ YES ☐ NO	16e.

17 NAME OF DIALYSIS PROVIDER	18. DIALYSIS PROVIDER NUMBER

TREATMENT INFORMATION—TRANSPLANT

19. DATE(S) OF TRANSPLANT	20 WAS THE PATIENT IN A HOSPITAL IN PREPARATION FOR, OR ANTICIPATION OF, A KIDNEY TRANSPLANT PRIOR TO THE DATE OF ACTUAL TRANSPLANTATION? ☐ YES ☐ NO		21. IF YES, ENTER DATE(S)
22. NAME OF HOSPITAL FOR ITEM 21	PROVIDER NO	23 NAME OF TRANSPLANT HOSPITAL IF DIFFERENT FROM ITEM 22	PROVIDER NO
24 CURRENT STATUS OF TRANSPLANT (IF b CHECKED ANSWER 25 OR EXPLAIN IN REMARKS) ☐ a. FUNCTIONING ☐ b REJECTED	25 DATE OF RETURN TO REGULAR DIALYSIS	CURRENT TREATMENT SITE ☐ a. HOME ☐ b. FACILITY	

MEDICAL CERTIFICATION

26 DO YOU CERTIFY THAT THIS PATIENT HAS REACHED THE STATE OF RENAL IMPAIRMENT THAT APPEARS IRREVERSIBLE AND PERMANENT AND REQUIRES A REGULAR COURSE OF DIALYSIS OR KIDNEY TRANSPLANTATION TO MAINTAIN LIFE? ☐ YES ☐ NO	SIGNATURE AND TITLE OF ATTENDING PHYSICIAN	DATE

CERTIFICATION OF SELF CARE DIALYSIS TRAINING

27. NAME, ADDRESS OF TRAINING PROVIDER	PROVIDER NO	28. DATE TRAINING BEGAN	29 TYPE OF TRAINING ☐ a. HEMODIALYSIS ☐ b PERITONEAL ☐ c CAPD
30 HAS THE PATIENT COMPLETED THE TRAINING PROGRAM? ☐ YES ☐ NO	IF NO, WHEN IS THE PATIENT EXPECTED TO COMPLETE THE PROGRAM?		31 DO YOU CERTIFY THAT THE PATIENT IS EXPECTED TO COMPLETE TRAINING SUCCESSFULLY AND SELF DIALYZE ON A REGULAR BASIS? ☐ YES ☐ NO

32. I CERTIFY THAT THE ABOVE SELF-DIALYSIS TRAINING INFORMATION IS BASED ON CONSIDERATION OF ALL PERTINENT MEDICAL, PSYCHOLOGICAL, AND SOCIOLOGICAL FACTORS AS REFLECTED IN RECORDS KEPT BY THIS TRAINING FACILITY, AND IS CORRECT

SIGNATURE OF PHYSICIAN PERSONALLY FAMILIAR WITH THE PATIENT'S TRAINING	TITLE	DATE

33. REMARKS

34 I HEREBY AUTHORIZE ANY PHYSICIAN, HOSPITAL, AGENCY OR OTHER ORGANIZATION TO DISCLOSE TO THE SOCIAL SECURITY ADMINISTRATION FOR PURPOSES OF REVIEWING MY APPLICATION FOR MEDICARE ENTITLEMENT UNDEP THE SOCIAL SECURITY ACT, ANY MEDICAL RECORDS OR OTHER INFORMATION ABOUT MY MEDICAL CONDITION

SIGNATURE OF PATIENT (SIGNATURE BY MARK MUST BE WITNESSED)	DATE

FORM HCFA-2728 -U4 (6-81)

*NOT REQUIRED TO OBTAIN A BENEFIT, WILL BE USED FOR STATISTICS ONLY

**NOT REQUIRED TO OBTAIN A BENEFIT BUT MUST BE COMPLETED FOR PURPOSES OF PROGRAM ADMINISTRATION

APPENDIX B

Patient Life Care Plan

ESRD NETWORK #3
PATIENT LONG TERM PROGRAM
Federal Register Section 405.2137(a)

The *purpose* of this form is to ensure that each individual receives the appropriate modality of care. The Plan should reflect that the selection of modality is based upon and compatible with the patient's medical, psychological and social needs.

PATIENT INFORMATION

NAME _____

ADDRESS _____

_____ TELEPHONE (___) _____

SEX: M F MARITAL STATUS _____ RACE _____

DATE ADMITTED to this Facility ___/___/___ TRANSFERRED FROM _____

MEDICAL DATA

PRIMARY ESRD DIAGNOSIS _____

DATE OF FIRST DIALYSIS ___/___/___

OTHER SYSTEM DISEASES/COMPLICATIONS _____

TREATMENT OPTIONS Check any of the following treatment options which were discussed and offered to patient:

1. HEMODIALYSIS: In-center☐ Home Train.☐ Self Care☐
2. PERITONEAL: CAPD☐ CCPD☐ IPD☐
3. NO DIALYSIS: ☐
4. TRANSPLANTATION: ☐

Which option was selected? _____

COMMENTS

A. SELF DIALYSIS OPTION

Check reason(s) why home dialysis or peritoneal dialysis not selected.

_____ Individual declined
_____ Family declined
_____ No helper available
_____ Other
_____ Psychosocial circumstances unsuitable
_____ Not medically suitable because _____

B. TRANSPLANT OPTION

This patient (check all that apply):

_____ Has been referred for transplant evaluation to
☐ UC ☐ PMC ☐ Sacto ☐ Other: _____
_____ Is on the cadaveric transplant registry
_____ Is awaiting a living related transplant
_____ Refuses to be referred or evaluated
_____ Is not referred to transplant for the following medical reasons

TEAM MEMBERS PARTICIPATING IN THE PLAN

Primary Physician/Medical Director _____ Date _____

Primary Nurse _____ Date _____

Social Worker _____ Date _____

Renal Dietitian _____ Date _____

PATIENT'S INFORMED CONSENT

I have had the opportunity to read this plan, and have been given the opportunity to participate in the planning process. At this date, I agree with the plan as specified. I understand that this plan is subject to change if medically necessary. I also understand this plan is subject to review at least annually and/or at either my request, or at the request of the facility staff.

I understand that I have the right to be referred for evaluation for any type of dialysis or transplant procedure.

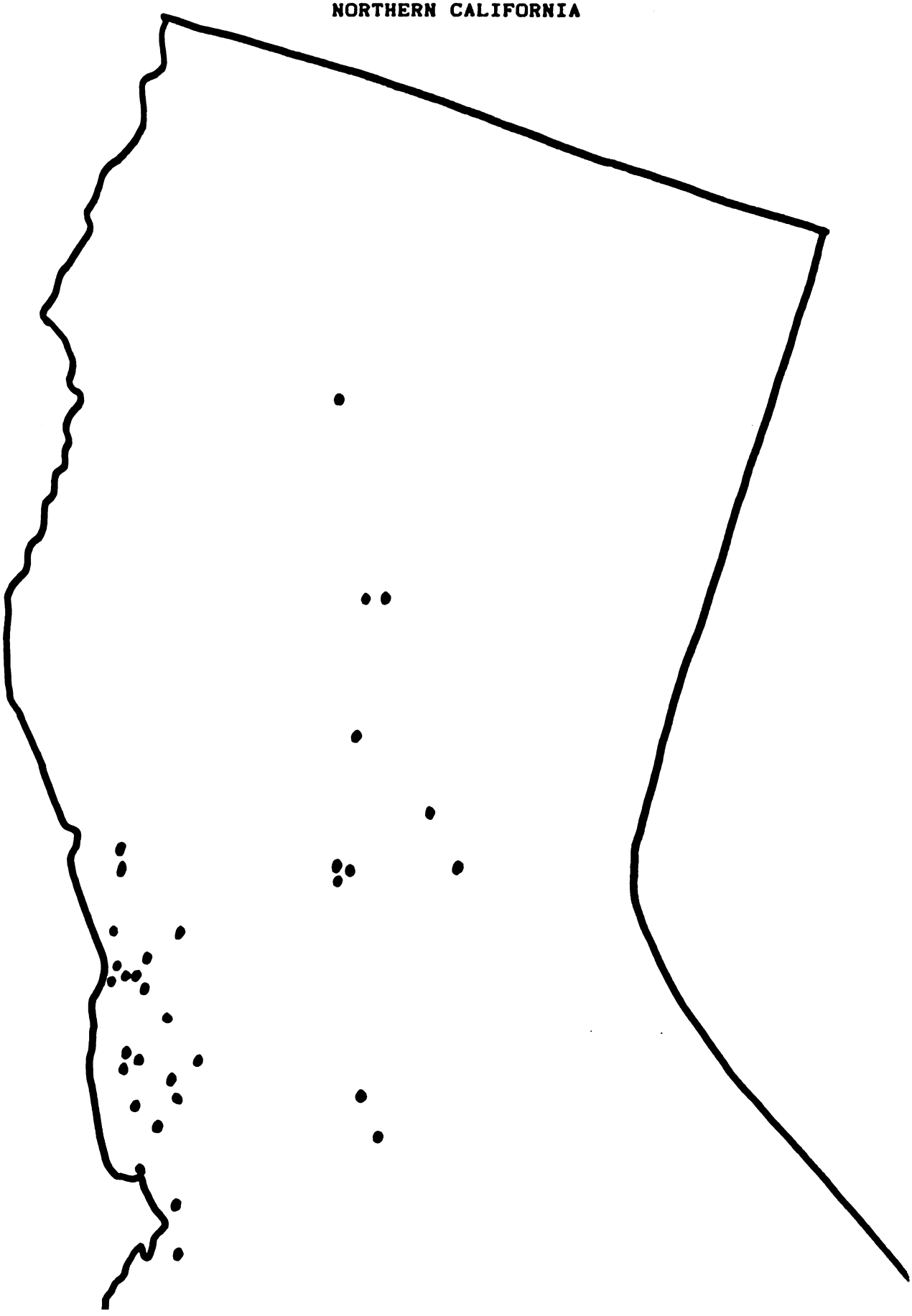
Signed _____ Date _____
(Patient or Representative)

APPENDIX C

Geographic Location of Facilities/

General Residence of Patients

ESRD FACILITY INTERVIEW SITES (N=33)
NORTHERN CALIFORNIA



APPENDIX D

Structured Interview

Pfettscher. Patient Interview
1

CODE #:_____

NAME:_____

ADDRESS:_____

_____

TELEPHONE #:_____

AGE:_____ SEX: M_____ F_____ MARITAL STATUS: S M D W Sep

ETHNICITY:_____ RELIGION:_____

MEDICAL INSURANCE: Private (Name)_____
Medi-Cal_____
Medicare_____
None_____

LEVEL OF EDUCATION: None_____
Completed Grade School_____
High School (Attended)_____(Graduated)_____
Technical School_____(type)
College (Attended)_____(Graduated)_____
Advanced college/university_____

EMPLOYMENT:(type of work)_____
Retired_____
Unemployed_____
Disability_____

INCOME:(previous year)_____

1. Who is your closest family member?

2. Do you have children?

3. If so, what are their ages?

4. With whom do you live?
Live alone_____
Live with spouse/family member_____specify
Live with significant other_____specify
Live with friends_____

5. Do you know what disease caused your kidneys to fail?
Yes_____ No_____

6. If so, what is the cause?

7. How long have you had this disease? (e.g., diabetes, lupus, hypertension or specific kidney disease)

8. How long (before starting treatment) did you know that you had kidney disease?

9. If you knew about your kidney disease, had you been seeing a kidney specialist (a nephrologist)?
Yes_____ No_____

10. If so, how long had you been seeing the kidney specialist?

11. If you were not seeing a nephrologist, had you been seeing a physician on a regular basis?
Yes_____ No_____

12. Was this physician a specialist?
Yes_____ No_____

13. What was his/her specialty?

If the patient knew he/she had kidney disease and had been seeing a physician prior to starting treatment, he/she will be asked the following questions.

14. Did the nephrologist tell you that you would require some type of replacement therapy for your kidney disease?
Yes_____ No_____

15. Do you recall what he told you?
Yes_____ No_____

16. Do you recall that he told you there were different types of treatment for kidney failure?
Yes_____ No_____

17. Do you recall what they were?
Yes_____ No_____

18. What were the types of treatment that were mentioned or discussed?

19. Did your doctor specifically make an appointment or spend special time with you during an appointment to talk about treatment?
Yes_____ No_____

20. Do you feel that your physician made a specific recommendation about which treatment would be best for you?
Yes_____ No_____

21. Do you recall your physician recommending that you begin treatment with a specific one?
Yes_____ No_____

22. Did your physician give you any written information about treatment for kidney failure?
Yes_____ No_____

23. If so, what information did you receive?

24. Did your physician refer you to anyone else to talk about treatment for kidney failure?
Yes_____ No_____

25. If so, to whom did you speak?

26. When you spoke with the physician about treatment for your kidney disease, were any family members or friends with you?
Yes_____ No_____

27. If so, who was with you at that time?

28. Did you tell family members about your kidney failure and the need for treatment?
Yes_____No_____

29. If so, who did you tell?

30. When did you tell them?

31. Did you tell any friends about your kidney failure and the need for treatment?
Yes_____No_____

32. If so, who did you tell?

33. Have you felt the need to keep your disease/treatment a secret?
Yes_____No_____

34. From whom have you kept it a secret?

35. Did you discuss your choices of treatment with any family members or friends (same as above and/or others) after you talked with the physician?
Yes_____ No_____

36. If so, with whom did you talk?

37. Did you ever know anyone (other family, friends, acquaintances) who had received treatment for kidney failure?
Yes_____ No_____

38. If so, who did you know?

39. Did you talk with that person before you started your treatment?
Yes_____ No_____

40. If so, do you think that discussion was useful to you? Why?
Yes_____ No_____

41. Did you speak with any other patient (someone you didn't know) before you started treatment?
Yes_____ No_____

42. If so, who arranged that meeting?

43. Do you think that discussion was useful to you? Why?
Yes_____ No_____

44. What was most useful to you from that discussion?

45. Were you admitted to the hospital to begin your dialysis treatments?
Yes_____No_____

46. Did you have a surgery to prepare you for your dialysis treatments?
Yes_____No_____

47. Was this surgery a major or minor one?

48. When you were in the hospital, did anyone specifically talk with you about receiving dialysis treatments?
Yes_____No_____

49. If so, who talked with you?

50. Did you have an opportunity to visit a dialysis unit before starting your treatments?
Yes_____No_____

51. Was that visit helpful to you?
Yes_____No_____

52. What was most helpful to you about it?

53. Do you believe that you had a choice about which treatment to use for your kidney failure?
Yes_____ No_____

54. Were you able to receive the treatment of your choice?
Yes_____ No_____

55. Do you believe that anyone influenced your decision about treatment choice?
Yes_____ No_____

56. If so, who influenced you?

57. Did this influence seem all right to you?
Yes_____ No_____

58. Explain why it was or was not all right.

59. Are you satisfied with your treatment choice or would you prefer to receive another type of treatment?
Yes_____ No_____

60. If not, which treatment would you prefer?

61. Did you ever consider not receiving any treatment for your kidney failure?
Yes_____No_____

62. When did you consider that option?

63. What made you change your mind?

64. What do you think would have happened if you had not started treatment?

65. Do you have any other comments to share about your choice of treatment for kidney failure and the decision-making process that you went through?

If the patient did not know that he/she had kidney failure before having to start treatment, they will be asked the following questions.

66. If you had not been seeing a doctor (nephrologist or other), why did you see a physician?

67. What kind of physician did you see?

68. Did he tell you that you were suffering from kidney disease/failure?
Yes_____ No_____

69. Did you go directly to a hospital emergency room because you were feeling ill?
Yes_____ No_____

70. Were you hospitalized when you began your treatment?
Yes_____ No_____

71. Had you ever been in the hospital before?
Yes_____ No_____

72. What was the reason you had been hospitalized before?

73. Had you ever had surgery before?
Yes_____ No_____

74. If so, what kind?

75. Did you have surgery when you began your treatment for kidney failure?
Yes_____ No_____

76. Was this a major or minor surgery?

77. When was this surgery performed?

78. Who told you that you would need treatment for your kidney failure?

79. How soon after you were told you that needed treatment did you have your first treatment?

80. Had you ever known anyone else who required treatment for kidney failure?
Yes_____ No_____

81. Who do you know?

82. What do you recall you were told about treatment for kidney failure?

83. Do you feel you had an opportunity to ask questions about this treatment or any alternatives?
Yes_____ No_____

84. To/with whom did you ask questions about treatment or discuss your treatment?

85. Were any family members or friends present when you were given information about treatment for kidney failure?
Yes_____ No_____

86. If so, who was with you at that time?

87. Did you discuss your decision with them?
Yes_____ No_____

88. Did they help you make any decisions about your treatment?
Yes_____ No_____

89. Did anyone give you any written information about treatment for kidney failure?
Yes_____ No_____

90. If so, who gave you information?

91. When did you receive this information?

92. Do you feel that you were given the opportunity to make any decisions about your treatment before it began?
Yes_____ No_____

93. What do you feel was the most important decision you had to make at that time?

94. Were you aware that there are different types of treatment for kidney failure when your treatment began?
Yes_____ No_____

95. Did you ask your physician or any other health professional about these different treatments?
Yes_____ No_____

96. Who did you ask?

97. If you did, what was the response?

98. If you did not, why not?

99. Have you felt the need to keep your disease/treatment a secret?
Yes_____No_____

100. From whom have you kept your disease/treatment a secret?

101. Do you believe that you had a choice about the type of treatment that you would receive for your kidney failure?
Yes_____ No_____

102. Would you prefer to have a different treatment than the one you are currently receiving?
Yes_____ No_____

103. If yes, which would you prefer to receive?

104. Do you believe you were given the opportunity and information necessary to make a decision about the type of treatment you desire for your kidney failure?
Yes_____ No_____

105. Explain why/why not?

106. Do you feel that anyone influenced the decision you made about treatment for kidney failure?
Yes_____ No_____

107. If so, who influenced you?

108. Was it all right that you were influenced by that person?

109. Did you ever consider not receiving any treatment for your kidney failure?
Yes_____ No_____

110. When did you consider that option?

111. What made you change your mind?

112. What do you think would have happened if you had not started treatment?

113. Do you have any other comments about the decisions you made in regard to your treatment for kidney failure?

APPENDIX E

Consent Form

University of California, San Francisco

Human Subjects Committee

UNIVERSITY OF CALIFORNIA SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT

PURPOSE AND BACKGROUND:
Susan Pfettscher, RN, MSN, a doctoral student in the School of Nursing at the University of California San Francisco is doing a study to determine how people with kidney failure make decisions about the choice of treatment they receive. Because I have recently begun treatment for my kidney failure or have given consent for someone else to receive ESRD treatment, I am being asked to participate in this study.

PROCEDURE:
If I agree to participate in this study, the following activity will occur: I will be interviewed by Ms. Pfettscher or another person designated by her at my treatment facility or at another place such as my home if it is more convenient for me. I will be asked some basic information about myself and will be asked questions about my illness, hospitalization(s), and the beginning of my treatment for kidney failure or that of the person for whom I am acting as decision-maker. I am free to refuse to answer any individual questions asked, and I may terminate this interview at any time. I also may choose to have someone else participate in this interview with me. Ms. Pfettscher or her designate may also review my medical record (or that of the patient whom I am representing) as necessary to obtain or verify information about my treatment. My interview will be tape-recorded and the interviewer may take written notes as we talk. All of the information I give will be kept confidential; my responses will be identified by a code number. This information will be kept in a locked file in Ms. Pfettscher's office.

RISKS/DISCOMFORTS:
The possible risks from my participation in this study are that I may become uncomfortable or upset as I recall my experiences of beginning treatment. I understand that I am free to express myself about this and that all of my comments will be kept totally confidential; they will not be shared with the doctors or nurses who care for me or the patient whom I represent.

BENEFITS:
There will be no direct benefit to me from participating in this study. It is hoped that this study will provide health care professionals with a better understanding of the process of beginning treatment for kidney failure patients.

REIMBURSEMENT:
I understand that I will not be paid for participating in this study.

QUESTIONS:
This study has been explained to me by Susan Pfettscher, RN, MSN or _____ (her designated interviewer) who has answered all of my questions about participating in this study. If I have other questions, I can contact Ms. Pfettscher or Dr. Anne Davis at (415) 476-1504. I may also contact the Committee on Human Research which has approved this study and which also protects volunteers who participate in research studies. I can reach their office by calling (415) 476-1814 between 8AM-5PM or by writing to the Committee on Human Research, University of California San Francisco, San Francisco, CA 94143.

CONSENT:
I have been given a copy of this consent form and a copy of Experimental Subject's Bill of Rights to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to participate or to withdraw at any point in this study without jeopardy to my medical care. If I wish to participate, I should sign this form.

_____ _____
DATE SUBJECT'S SIGNATURE

CHR APPROVAL # H1358-05578-01

EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to me for research purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told the other choices I have and how they may be better or worse than being in the study,

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.

9) To receive a copy of the signed and dated consent form,

10) To be free of pressure when considering whether I wish to agree to be in the study.

APPENDIX F

Consent Forms

Two Other Human Subjects Committees

SANTA CLARA VALLEY MEDICAL CENTER

SOCIOCULTURAL AND ECONOMIC VARIABLE IN ESRD TREATMENT DECISION-MAKING
CONSENT TO BE A RESEARCH SUBJECT

PRINCIPAL INVESTIGATOR: Susan A. Pfettscher, RN, MSN, Doctoral Candidate, Department Of Mental Health, Community, and Administrative Nursing, School of Nursing University of California San Francisco, San Francisco, CA 94143, Telephone #: (415) 476-1504.

PURPOSE: Ms. Pfettscher is doing a study to determine how people with kidney failure make decisions about the type of treatment they receive. Because I have recently begun treatment for kidney failure or have given consent for someone else to receive ESRD treatment, I am being asked to participate in this study.

PROCEDURE: If I agree to participate in this study, the following activity will occur: I will be interviewed by Ms. Pfettscher or another person designated by her at my treatment facility or at another place such as my home if that is more convenient for me. I will be asked some basic information about myself and will be asked questions about my illness, hospitalization(s), and the beginning of my treatment for kidney failure or that of the person for whom I am acting as decision-maker. I am free to refuse to answer any individual questions asked, and I may terminate this interview at any time. I also may choose to have someone else participate in this interview with me. My interview will be tape-recorded and the interviewer may taken written notes as we talk. Ms. Pfettscher or her designate may also review my medical record (or that of the patient whom I am representing) as necessary to obtain or verify information about my treatment.

RISKS/DISCOMFORTS: The possible risks from my participation in this study are that I may become uncomfortable or upset as I recall my experiences of beginning treatment. I understand that I am free to express myself about this and that all of my comments will be kept totally confidential; they will not be shared with the doctors or nurses who care for me or the patient whom I represent.

BENEFITS: There will be no direct benefit to me from participating in this study. It is hoped that this study will provide health care professionals with a better understanding of the process of beginning treatment for kidney failure patients. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

COSTS: Participation in this study is on a voluntary basis and does not involve any cost to you. I understand that I will not be paid for participating in this study.

CONFIDENTIALITY: All of the information I give will be kept confidential; my responses will be identified by a code number. None of my

responses will be shared with the doctors and nurses who care for me or the person I represent. The audiotape and written notes taken by Ms. Pfettscher or her designate will be kept in a locked file in Ms. Pfettscher's office.

COMPENSATION: It is the policy of the California Institute for Medical Research not to provide reimbursement for medical care or any form of compensation in the event of any physical or psychological injury sustained in the course of this research study. If you are injured as a result of your participation in this study, you should contact the principal investigator to determine what alternatives for care are available. This disclaimer does not affect any right I might have to compensation or medical treatment from some other source or sources.

SUBJECT/PATIENT RIGHTS: I understand that I am free to withdraw my consent and discontinue participation in the study at any time without prejudice to me or effect on my medical care. I have been made aware of the discomforts and inconveniences involved in this research study. My questions have been answered and should I have additional questions, I may contact SUSAN PFETTSCHER, RN, MSN at (415) 476-1504. If I am not satisfied with the manner in which this study is being conducted, I may contact the Research and Human Subjects Review Committee which is concerned with protection of volunteers in research projects. The Committee may be reached by calling the office from 9:00AM - 5:00PM Monday through Friday at (408) 998-4554, or by writing to the Research Committee at the California Institute for Medical Research, 2260 Clove Drive, San Jose, California 95128.

WITNESSING AND SIGNATURES: The nature, demands, risks, and benefits of the project have been explained to me as well as the type of treatment as known and available. I understand what my participation involves. Furthermore, I understand that I am free to ask questions and withdraw from the study at any time without affecting my medical care. I also understand that I will receive a copy of the signed and dated consent form and the Experimental Subject's Bill of Rights. I hereby voluntarily consent and offer to take part in this study.

_____	_____
Signature of Subject	Date Signed
_____	_____
Signature of Witness	Date Signed

I have carefully explained to the subject the nature of the above study. I hereby certify that to the best of my knowledge the subject signing this consent form understands clearly the nature, demand, risks, and benefits involved in participating in this study. A medical problem or language barrier has not precluded a clear understanding of the subject's involvement in this study.

_____	_____
Signature of Investigator	Date Signed

IRB Approval # 0/26/90-04

SOCIODEMOGRAPHIC AND ECONOMIC VARIABLES IN ESRD TREATMENT DECISION-MAKING
CONSENT TO BE A RESEARCH SUBJECT

You are invited to participate in a study of patient decision-making about treatment for End Stage Renal Disease. We hope to learn what the issues and problems are that patients experience as they make decisions about treatment and what is useful or not useful to them as they make such decisions. You were selected as a possible participant in this study because you or a significant other has recently (within the past 3 months) begun treatment for renal failure.

If you decide to participate, Susan Pfettscher or her associates will interview you about the circumstances of the diagnosis of renal disease and the thoughts you had and decisions you made about beginning treatment for yourself or your significant other. This interview will be audiotaped to allow for later analysis of your responses. It will take less than one hour to complete. The only potential distress or discomfort that participating in this research could cause you is to recall the circumstances of learning about your renal failure and the need for treatment. While there are no benefits to you individually from this study, the researcher hopes to determine what influenced your decision-making process and what made it easier or more difficult for you as treatment was begun. This information will allow health care professionals to provide better care for others who undergo dialysis treatment. WE CANNOT AND DO NOT GUARANTEE OR PROMISE THAT YOU WILL RECEIVE ANY BENEFITS FROM THIS STUDY.

Your identity will be protected; you will be assigned a code number at the time of your interview. Your answers during the interview will remain totally confidential. They will not be shared with your doctors, nurses, or any others involved in your care. If you do not want to be interviewed in the dialysis unit, we can make arrangements for you to be interviewed in your home or at any other location you prefer. The information obtained from you and the others participating in the study will be published in the appropriate journals and presented at meetings to educate health care professionals who care for renal failure patients.

You will receive no payment for participating in this study; there will be no cost to you for participating in this study.

Your decision about whether or not to participate in this study will not affect your medical care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time during the interview without any effect on your care. You may also choose not to answer any individual question during the interview if you wish.

---------- ----------

Signature Date

SOCIODEMOGRAPHIC AND ECONOMIC VARIABLES IN ESRD TREATMENT
TREATMENT DECISION-MAKING

If you have any questions, we expect you to ask us. If you have any additional questions after the interview, I will be happy to answer them. You may call me at (415) 476-1504.

All forms of medical diagnosis and treatment--whether routine or experimental--involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the researcher will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for additional medical or other costs. Additionally, Stanford is not responsible for research and medical care by other institutions or personnel participating in this study. You do not waive any liability rights for personal injury by signing this form. For further information, please call (415) 723-5244 or write the Administrative Panel on Human Subjects in Medical Research at Medical School Office Building, Room C-051, Stanford, CA 94305. In addition, if you are not satisfied with the manner in which this study is being conducted or if you have any questions concerning your rights as a study participant, please contact the Human Subjects Office at the same address and telephone number.

VA Patients Only: In the unlikely event you are injured as a result of participation in this study, Palo Alto Veterans Administration Medical Center will furnish humanitarian emergency medical care (for non-veteran participants) or medical care (for veteran participants) as provided by federal statute. Compensation for such injury may be available to you under the provision of the Federal Tort Claim Act (for non-veteran and veteran participants) and/or 38 U.S.C. (for veteran participants). For further information, contact the VA District Counsel at (415) 556-4656.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION, THAT YOU HAVE DISCUSSED THIS STUDY WITH THE PRINCIPAL INVESTIGATOR AND HIS OR HER STAFF, THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED, AND THAT A COPY OF THIS FORM HAS BEEN GIVEN TO YOU.

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Signature Date

Signature of Investigator or Witness

FOR REFERENCE

NOT TO BE TAKEN FROM THE ROOM

CAT. NO. 23 012

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