# Chapter V

# ESRD Treatment Modalities

Renal replacement therapy options for patients with ESRD include three major categories: renal transplantation, hemodialysis, and peritoneal dialysis. For each of these therapies several subcategories exist as described below. Over time a large fraction of patients move from one treatment modality to another. The following sections review the different treatment options, describe data sources and analyses, discuss trends in the use of different modalities, and examine time trends and demographic differences in patterns of use of the modalities as well as changes in modalities for incident ESRD patients.

## Brief History of ESRD Therapies

Until 1960 end-stage renal disease was a fatal condition. That year Belding Scribner utilized a new vascular access technology developed with Wayne Quinton on the first chronic renal failure patient to allow chronic treatment with hemodialysis. Yet attempts at dialysis treatment for acute renal failure had begun much earlier and proved successful, when Willem Kolff developed the first clinically effective artificial kidney in 1944, using newly developed technologies of cellophane as a dialysis membrane and heparin as an anticoagulant (Peters). For hemodialysis therapy a central dialysate delivery system, followed by a proportioning system, was developed. Equipment for home hemodialysis soon became a necessity (Peters). Blood access was further facilitated by the Cimino-Brescia internal arterio-venous fistula which has virtually replaced the Quinton-Scribner shunt. In membrane technology major advances have been achieved regarding biocompatibility and high flux hemodialysis.

Peritoneal dialysis had been used for acute renal failure as early as 1938. Yet, unavailability of a long-term access prevented its use for chronic renal failure. Tenckhoff utilized newly available silicone rubber to develop, during the 1960s, a soft catheter, with Dacron cuffs for safer long-term access to the peritoneal cavity. He also described the technique for percutaneous introduction of the cuffed catheter. During the late 1970s continuous ambulatory peritoneal dialysis (CAPD) with long dwell times was shown to be an effective alternative to intermittent peritoneal dialysis treatments.

Renal transplantation also became a clinical reality during the 1960s (Hamilton). Surgical technique had been far in advance of immunological theory. In 1954 the first renal transplant achieved sustained functioning of a graft from an identical twin ( Murray); drug therapy was developed later which modified the immune response to allow transplantation from non-identical donors. Tissue typing came into routine use during the 1960s as did the direct crossmatch between donor cells and recipient serum. More recently, improved immunosuppression with cyclosporine has further expanded treatment prospects and graft survival (Merion; Kahan; Sheil). Despite these developments, transplantation in the United States has shown little growth since 1986 due to limited availability of donor organs (Prottas).

It was not until 1973 that nation-wide funding was earmarked for dialysis programs after Congress enacted Medicare coverage for end-stage renal disease as part of the Social Security Amendments of 1972 (Fox; Rettig, 1982). Several legislative changes have been made in Medicare's ESRD program since 1972. Most have sought to encourage reduction in treatment costs through shifts in modality to home dialysis and changes in payment methods (HCFA). A recent report from the Institute of Medicine considered the possible association between reductions in the reimbursement rate for dialysis treatments (i.e., no increases in this rate over the 1980s, despite inflation) and reduced quality of care (Rettig, 1991). Some additions to coverage have also been made, notably for the first year of immunosuppressive drugs after transplantation and for erythropoietin therapy to treat anemia in dialysis patients (Erslev).

Today, approximately 200,000 ESRD patients are alive in the United States as a result of ESRD therapy, compared to an estimated 11,000 patients in 1973 (Evans, 1981). Providing this treatment is, however, very costly (see Chapter III). Opinions differ about ESRD patients' quality of life, but they themselves report general satisfaction (Evans, 1985). Over time, the USRDS hopes to help improve the understanding of quality-of-life issues for the various modalities of ESRD care, as well as the biomedical efficacy and outcomes of different treatments.

## Renal Replacement Therapy Options

**Renal transplantation** may be either from a living donor or a cadaveric donor. Living donors are almost always blood relatives, although there has been a slight increase in recent years in living unrelated transplants. A cadaver donor is a person who is brain dead, such as an accident victim, and whose circulation and respiration are maintained until organ removal (“harvesting”). Whereas transplantation from a living related donor can be scheduled in advance and may be done as an initial or early therapy, transplantation from a cadaver donor usually requires a prolonged waiting time, averaging one to two years. Survival of the transplanted kidney (graft or allograft) is influenced by a variety of factors (Opelz; Iwaki; Braun) such as HLA matching, duration of organ preservation (warm and cold ischemia time) following harvesting of the organ, presence or absence of panel reactive antibodies, patient demographic factors, and immunosuppressive drug regimens.

These factors are described further in Chapter VIII.

**Hemodialysis** achieves removal of toxins, electrolytes, and excess fluid via extracorporeal circulation of blood through a dialyzer (artificial kidney). Treatments are usually scheduled for three to four hours, three times weekly. A vascular access, via an arterio-venous fistula, vascular graft, or vascular catheter, is required. The treatment is performed in a hospital-based or freestanding dialysis facility as “center hemodialysis”; or at home as “home hemodialysis” after the patient and an assistant (often the spouse) undergo several weeks of training. Home hemodialysis encourages patient independence, allows freedom to schedule dialysis to meet patient convenience, and is associated with the best quality of life among dialysis therapies.

**Peritoneal dialysis** (PD) provides an alternative dialytic therapy that requires placement of a catheter into the abdominal cavity and repeated instillation and drainage of sterile dialysate. Each time the dialysate is drained, toxins and electrolytes. are removed or equilibrated. Fluid removal is achieved by use of hypertonic dialysate solutions. Several peritoneal dialysis options are available. Intermittent PD (IPD) requires frequent exchanges of dialysate, usually in thrice-weekly sessions lasting 10 to 12 hours. IPD can be performed in-center or at home. Since the late 1970s, home IPD has been generally replaced by continuous ambulatory PD (CAPD) as the preferred PD modality. For CAPD, the patient usually performs four exchanges with prolonged dwell times of the dialysate on a daily basis. Continuous cycling PD (CCPD) is also usually a home treatment and utilizes several exchanges through a programmed machine (cycler) every night, with one long dwell time throughout the day. The utilization of CCPD has increased in recent years, but CCPD use accounts for only one tenth of PD use. Other variations of home PD are in use (Twardowski) but are used too infrequently to be discussed further in this report. PD is used frequently for patients who prefer the independence of self-care or for those who have difficulty with vascular access or other aspects of hemodialysis. Thus, there may be a selection into PD of both patients who are stable and independent and those who are unstable and poorly tolerant of hemodialysis (USRDS, 1992). The fraction of CAPD patients that switches to hemodialysis during the first few years of treatment is much larger than the fraction of hemodialysis patients switching to CAPD (USRDS, 1991).

## Data Sources on Modality Use

The longitudinal determination of the treatment modality for individual patients in the USRDS database requires a complex analytical process that examines a variety of data sources, including reports from the facility surveys of the ESRD Networks and HCFA billing summaries, that are available in the USRDS database for each patient. This process is described in greater detail in Chapter XV. For many cases, treatment modality and dates of change in modality must be inferred indirectly from sources such as

**Point Prevalence Counts by Modality, Data Source, and Year, 1982-1991**

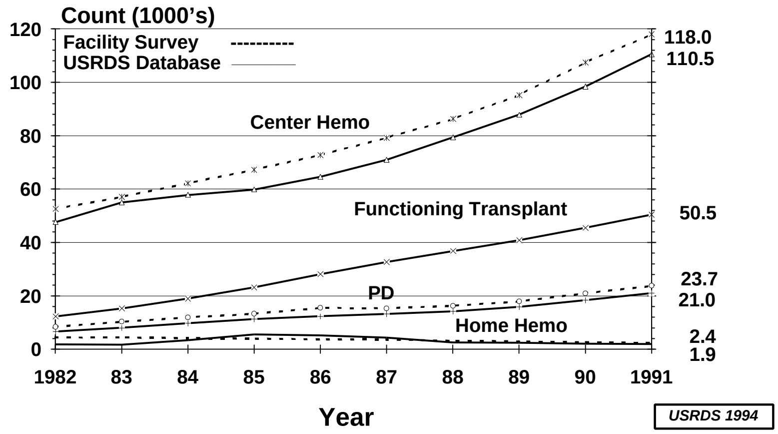



**Figure V-1**

*Point Prevalence counts of ESRD patients alive on Dec. 31, by treatment modality, data source, and year, 1982-1991. Differences in counts are shown between the USRDS database and the HCFA Annual Facility Survey. Percentages include Puerto Rico and U.S. Territories. USRDS includes Medicare patients only. Source: Reference Tables C1, I11.*

the billing tapes. Because the USRDS is continually refining this process, slight variations between the modality data reported in different annual data reports should be expected.

## Point Prevalence by Modality

The treatment modality in use for all ESRD patients on December 31 is obtained from two sources: 1) the USRDS longitudinal patient treatment files ("data base") and 2) the HCFA-mandated year-end facility surveys. The latter includes both Medicare and non-Medicare patients and reports the year end point prevalence. Figure V-1 shows these numbers for the years 1982 to 1991. The undercount in the USRDS database is in the 6 to 7 percent range which corresponds with the observation that about 93 percent of ESRD patients are covered by Medicare. There has been a steady increase in the overall number of patients treated, and in the number of patients on each modality. As one exception, the small home hemodialysis group showed a slight decrease in recent years. Throughout the period, patients treated with center hemodialysis constituted the largest group; patients with a functioning renal transplant were the second largest group. Transplant recipients who lost their transplant function and returned to dialysis are shown in the appropriate dialysis group for the year end prevalence counts.

CAPD/CCPD combined has been the third most common form of ESRD therapy. During the early 1980s, the use of CAPD and CCPD showed a relatively steep increase (not shown). The use of CCPD has been increasing during the second half of the 1980s, and now accounts for approximately 10 percent of the combined CAPD/CCPD category.

## Distribution of Prevalent ESRD Patients by Treatment Modality and Year, 1982-1991

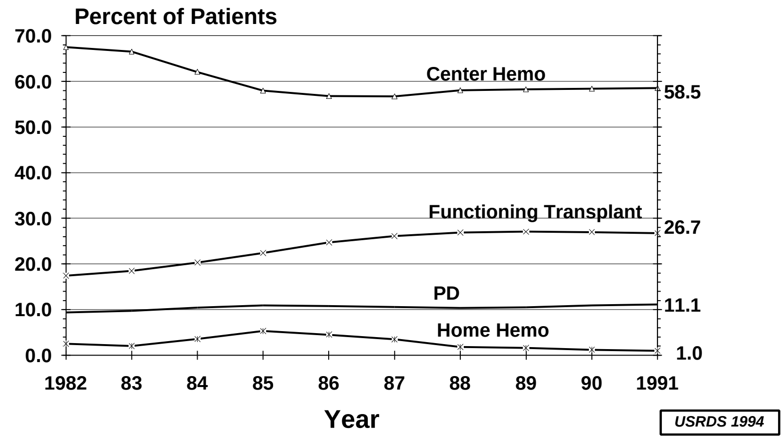



**Figure V-2**

*Percent distribution of ESRD patients alive on December 31, by treatment modality and year, 1982-1991. Percentages include Puerto Rico and U.S. Territories. Medicare patients only. Source: Reference Table C5.*

Only a small fraction of patients utilize home hemodialysis, and this therapy has shown a gradual decline since 1985. Intermittent peritoneal dialysis, usually performed in a dialysis center, is less commonly used. Patients treated with this modality and patients with other, unknown and unstable dialysis accounted for 2.9 percent of ESRD patients at the end of 1991. Patients who initiated dialysis therapy during the last two months of the most recent year, 1991, are automatically placed in this category according to definitions outlined in Chapter XIV. The two to three percent of patients for whom the modality cannot be determined from available data are included under "other/unknown" and unstable dialysis so that all prevalent patients are accounted for in this analysis.

Figure V-2 shows the same data as a percent distribution for each year. This figure clearly demonstrates that the fraction of patients with a functioning renal transplant increased until 1988. This was due to both a rise in the number of transplants performed and improvements in graft survival (see Chapter VIII). However, the relatively constant percentage since 1988 is a reflection of the scarcity of available organ donors. The fraction of patients treated with CAPD/CCPD has been fairly constant since the mid 1980s. During 1982-91, center hemodialysis decreased relative to other modalities (Figure V-2), yet its total numbers increased (Figure V-1). Since 1988, the percent distribution for all modalities has essentially stabilized. At the end of 1991, peritoneal dialysis patients accounted for 11 percent of all ESRD patients and 15 percent of all dialysis patients.

The subgroups of peritoneal dialysis patients are shown in Figure V-3. Whereas the fraction treated by CAPD

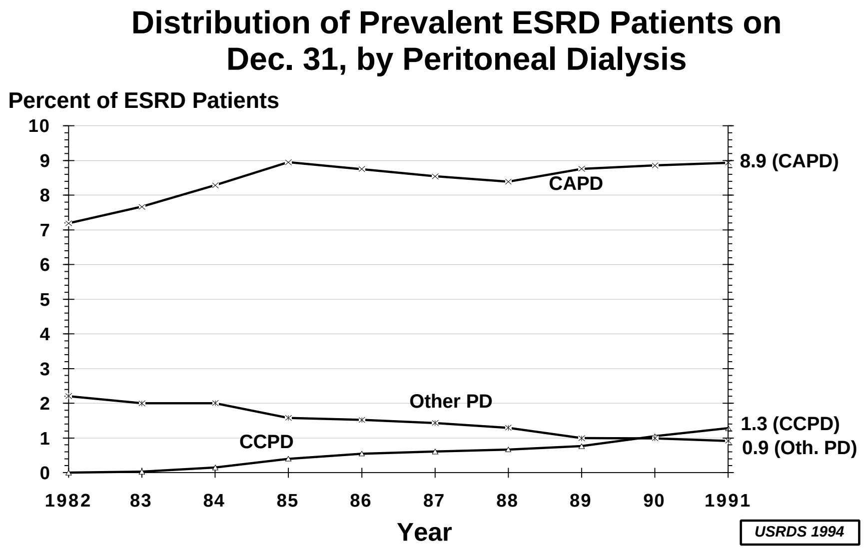



**Figure V-3**

*Percent distribution of Prevalent ESRD patients on December 31, by type of Peritoneal Dialysis and year. The three curves in this figure sum to equal the PD curve in Figure V-2. Percentages include Puerto Rico and U.S. Territories. Medicare patients only. Source: Special Analysis.*

remained fairly constant since 1985, there continued to be a substantial increase in the proportion of patients treated by CCPD. In 1991 CCPD accounted for 11.6 percent of all peritoneal dialysis. The fraction treated with other peritoneal dialysis decreased during the 1980s.

Regional information is provided as actual patient counts and percentages of all ESRD patients alive at the end of 1991 by treatment modality in Table V-1. The geographic regions are those of the 18 ERSD Networks. Compared to the national summary data (totals), this table shows variations for certain regions. The percentage of patients treated with CAPD ranges from 8.5 to 20.7 percent with relatively high percentages in Midwestern states. This may be related, in part, to the distances of patients from the nearest dialysis facility as analyzed in the USRDS 1991 Annual Data Report. The variations in CCPD use do not parallel those for CAPD. The proportion of patients with a functioning transplant is reported here only for ages 0-64 years. This avoids the false impression that regions with high fractions of geriatric patients would show low transplantation rates. The fraction with a functioning transplant shows a two fold variation by region (24.7 to 50.1 percent). While it is difficult to fully explain the observed differences, it is important to describe them to allow regional efforts to be directed towards improved patient access to all modality options.

## Living Patients on December 31, 1991, by Treatment Modality, by Network

| Network | Total Count | Percent with a Functioning Transplant Age 0-64 | Percent of Dialysis Patients Receiving Center Hemo | Home Hemo | CAPD | CCPD |
|---|---|---|---|---|---|---|
| Network of New England, Inc. (CT) | 8,422 | 46.5 | 76.8 | 1.6 | 14.3 | 2.1 |
| Network of New York, Inc. (NY) | 13,473 | 29.9 | 77.3 | 1.9 | 13.3 | 1.3 |
| Trans-atlantic Renal Council (NJ) | 8,231 | 24.7 | 78.1 | 1.2 | 14.0 | 2.2 |
| ESRD Network Organization No. 4 (PA) | 10,423 | 39.8 | 80.9 | 1.1 | 11.0 | 1.5 |
| Mid-atlantic Renal Coalition (VA) | 11,751 | 31.9 | 82.1 | 0.9 | 9.7 | 0.6 |
| Southeastern Kidney Council, Inc. (NC) | 14,823 | 27.2 | 81.7 | 0.7 | 10.5 | 3.2 |
| ESRD Network of Florida, Inc. (FL) | 10,672 | 33.3 | 85.3 | 0.7 | 8.9 | 2.1 |
| Network 8, Inc. (MS) | 10,346 | 31.3 | 81.4 | 2.6 | 11.0 | 1.6 |
| Tri-state Renal Network, Inc. (IN) | 15,163 | 43.4 | 73.7 | 1.2 | 17.6 | 1.0 |
| Renal Network of Illinois (IL) | 8,584 | 39.2 | 83.4 | 0.7 | 9.1 | 1.0 |
| Renal Network of the Upper Midwest (MN) | 13,968 | 50.1 | 71.1 | 1.2 | 17.5 | 1.6 |
| ESRD Network Organization No. 12 (MO) | 7,240 | 46.7 | 71.3 | 2.4 | 20.7 | 2.1 |
| ESRD Network Organization No. 13 (OK) | 7,486 | 30.9 | 82.2 | 1.2 | 12.6 | 2.0 |
| Network of Texas, Inc. (TX) | 13,526 | 31.9 | 85.3 | 1.1 | 8.5 | 1.9 |
| Inter-mountain ESRD Network, Inc. (CO) | 7,268 | 41.3 | 77.9 | 2.1 | 12.5 | 2.9 |
| Northwest Renal Network (WA) | 5,629 | 45.6 | 70.0 | 9.0 | 14.6 | 1.8 |
| Trans-pacific ESRD Network (N-CA) | 9,003 | 38.7 | 84.6 | 0.6 | 10.0 | 1.5 |
| Southern California ESRD Network (S-CA) | 12,583 | 35.9 | 86.6 | 0.2 | 8.8 | 1.5 |
| TOTAL | 188,591 | 36.7 | 80.0 | 1.4 | 12.2 | 1.7 |

*Percentages sum to almost 100% across rows, the remainder is accounted for by other or unknown dialysis. (Total=95.3%)*

*Total N's do not include patient data for whom network is unknown. (Total=4.7%)*

**Table V-1**

The activity in renal transplantation by year is shown as the numbers of living related and cadaveric renal transplants performed per year for 1983-92 in Figure V-4. These data are based on the Annual Facility Survey completed by all providers at the end of each year (see Chapter XI). Although the number of living related transplants has increased only slightly since 1982, the number of cadaveric transplants performed per year increased steeply before 1986. However, there was only a minute increase between 1986 and 1992. The relatively stable number of cadaveric transplants performed in recent years contrasts sharply with the steeply increasing number of patients on the waiting list for cadaveric transplants. In fact, the increase from 1991 to 1992 for patients on a waiting list was 18.4 percent which exceeded the average rate of rise for earlier years (Figure V-4). This widening gap between supply and demand for kidneys from 1986 through 1992 has serious implications, since it

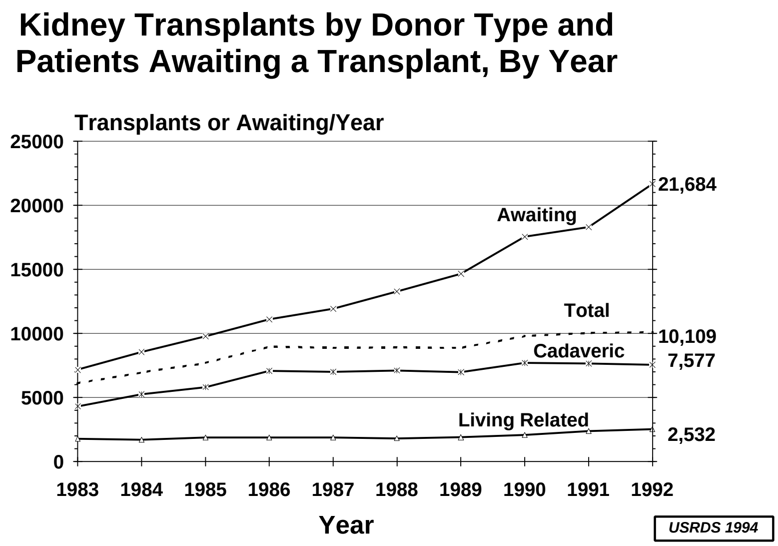



**Figure V-4**

*Counts of kidney transplants performed by (Medicare and Non-Medicare) patients donor type and count of patients awaiting cadaveric transplant by year, 1983-1992. Source: Reference Table I.10.*

causes the waiting period for ESRD patients desiring a cadaveric transplant to increase even further. There is a clear need for increased cadaveric organ donation in the U.S. Additionally, an increase in related donor transplantation would appear desirable given its superior survival figures (Chapter VIII). More details of the demographics of transplant patients and donors is provided in Chapter VIII.

## Modality Utilization by Demographic Groups

Utilization of the various treatment modalities differs by patient characteristics. The demographics of access to transplantation has been well-studied (Gaylin; Webb) and will not be discussed in detail in this chapter. For pediatric age groups, a detailed discussion of treatment modalities is provided in Chapter IX..

As shown in Table V-2, center hemodialysis was the most common form of ESRD therapy (59 percent) among prevalent patients at the end of 1991. Functioning renal transplant accounted for 26.7 percent, CAPD/CCPD for 10.2 percent and home hemodialysis for 1 percent of all ESRD patients treated at the end of 1991. Only 2.9 percent of prevalent patients were treated by other forms of PD or by unstable or unknown dialysis.

By age group, younger patients have a higher fraction of functioning transplants than older patients. Compared to 60.9 percent of ESRD patients with functioning transplants in the under 20 age group, there were 26.3 percent in the 45-64 age group and only to 3.8 percent in the 65 year and older group. The percentage using CAPD/CCPD appears relatively stable across age groups ranging from 9.7 to 13.8 percent. Hemodialysis is used infrequently in the pediatric ages accounting for 17.2 percent for in center and home hemodialysis combined. By contrast, the oldest age group (>65 years) was primarily treated by center hemodialysis.

## Treatment Modality Summary by Age, Sex, Race, and Primary Disease, 1991

| | Percent* | | | | |
|---|---|---|---|---|---|
| **Patient Characteristic** | **Functioning Transplant** | **Center Hemo** | **Home Hemo** | **CAPD/ CCPD** | **Other PD/ Unknown** |
| All Patients | 26.7 | 58.8 | 1.0 | 10.2 | 3.1 |
| Age 0-19 | 60.9 | 16.9 | 0.3 | 13.8 | 7.8 |
| Age 20-44 | 47.6 | 38.4 | 0.9 | 9.7 | 3.1 |
| Age 45-64 | 26.3 | 58.6 | 1.1 | 10.4 | 3.4 |
| Age 65+ | 3.8 | 83.1 | 0.9 | 10.2 | 1.7 |
| Male | 29.7 | 56.0 | 1.0 | 9.8 | 3.2 |
| Female | 23.1 | 62.2 | 0.9 | 10.6 | 3.0 |
| Native American | 23.4 | 60.7 | 1.4 | 11.0 | 3.3 |
| Asian/Pacific Islander | 27.1 | 61.7 | 0.7 | 8.5 | 1.9 |
| Black | 13.7 | 75.0 | 0.6 | 7.9 | 2.5 |
| White | 32.9 | 51.3 | 1.1 | 11.3 | 3.1 |
| Diabetes | 18.4 | 66.7 | 0.6 | 11.4 | 2.3 |
| Hypertension | 12.7 | 74.5 | 0.6 | 10.1 | 1.7 |
| Glomerulonephritis | 40.4 | 45.5 | 1.2 | 10.6 | 2.0 |
| Cystic Kidney Disease | 39.4 | 45.5 | 2.0 | 10.4 | 2.2 |
| All Other | 32.2 | 53.3 | 1.2 | 10.6 | 2.7 |

** Percentages add across to ~ 100*

*Source: Reference Tables C2, C3, C5*

**Table V-2**

By race, there are also clear differences in modality usage. In the categories of functioning transplant the percentages are more than twice as large for whites compared with blacks (32.9 percent vs. 13.7 percent) whereas the other two racial groups have an intermediate position. The differences for the fractions with functioning transplants are in part due to differences in transplantation rates (Held) and in transplant graft and patient survival (see Chapter VIII).

The use of CAPD/CCPD when re-analyzed as the percentage of only dialysis patients, also had relatively low percentages for blacks (9.2 percent) and Asian Americans (11.6 percent), whereas the corresponding percentages were comparatively high for Native Americans (14.3 percent) and whites (16.8 percent). Home hemodialysis was used by 3.4 percent of Native American dialysis patients compared to 1.6 percent for whites and 0.7 percent for blacks. For Native Americans, CAPD/CCPD and home hemodialysis represents a relatively high fraction of dialysis patients. One may speculate that this observation may be explained in part by relatively long driving distances to dialysis facilities.

Males have a higher percentage of functioning transplants (29.7 percent) compared to females (23.1 percent) which agrees with the finding of greater transplantation rates for males (Gaylin; Webb). As a fraction of only dialysis patients, males and females utilize CAPD/CCPD at a nearly equal percentage (14.1 and 13.8, respectively). Male dialysis patients are only slightly more likely to be on home hemodialysis (1.4 percent) than females (1.2 percent).

Table V-2 also shows data for patient groups with the four major primary causes of ESRD: diabetes, hypertension, glomerulonephritis and cystic kidney disease. The latter two groups had a much higher fraction with a functioning transplant (nearly 40 percent compared to 13-18 percent in the other two groups). Use of CAPD/CCPD appears to be similar by diagnosis group, but as a fraction of only dialysis patients it is relatively high in the glomerulonephritis group (17.7 percent) and relatively low in the hypertension group (11.6 percent). Among dialysis patients, home hemodialysis is used more than twice as much in the glomerulonephritis and cystic disease groups (2.0 - 3.3 percent) as in the diabetes and hypertension groups (0.7 percent each), yet these percentages are 5 to 19 times lower than those for CAPD/CCPD.

## Sequential Modality Uses

After the start of ESRD therapy many patients change modalities over time. The pattern of these changes in modality can be very simple, such as hemodialysis followed by transplantation, or it can be very complex, with multiple switches among dialysis modalities and multiple transplants with periods of dialysis following graft failure. This report examines the modality histories of a cohort of patients who started ESRD therapy during the years 1985 and 1986 and follows individual patients during their first three years of treatment (Daugirdas).

This method utilizes time-series plots showing the distribution of treatment modality and death by month since start of therapy for this cohort of patients. Death is included as a category to give a more complete picture of what happened to the cohort. The sample size remains constant, since a patient can always be classified into one of the mutually exclusive categories (treatment modalities and death). Note that modality is determined for each patient at the end of each month after the patient's onset of ESRD.

Figure V-5 presents these modality histories for the cohort of all patients starting therapy in 1985 and 1986. Treatment modalities are recorded by patient at the end of each month, producing generally smooth, continuous curves. The “y” axis represents percent of total patients, and the “x” axis represents months since onset of ESRD.

The stacked time-series plot has also been used by the USRDS (USRDS, 1991) and the European Dialysis and Transplant Association registry “Selwood analysis” (Kramer) as a standard modality graph to depict the dynamics of change over time as well as the distribution at each point in time.

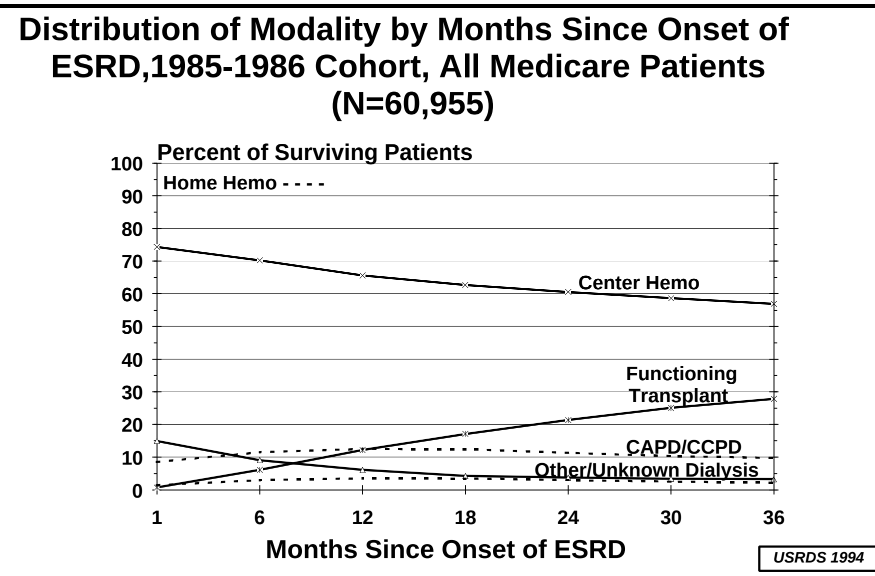



**Figure V-5**

*Percent distribution of surviving patients by months since start of ESRD treatment by treatment modality for all patients starting treatment in 1985-1986. Medicare patients only. Source: 1993 ADR*

Figure V-5 shows that center hemodialysis is the dominant modality throughout. The curve for center hemodialysis in Figure V-5 remains larger than the curves for all of the other modalities combined, but decreases as patients die or receive transplants. The upward slope of the transplant curve in Figure V-5 shows a continually increasing proportion of patients with a functioning transplant over time. CAPD/CCPD is, during the first year, larger than the transplant group but subsequently is exceeded by functioning transplants. The use of CAPD/CCPD and home hemodialysis show slight declines over the first three years of ESRD. Other dialysis and unknown modality decline steadily over time in part due to better identification of the patients' modality, particularly after the first three months when patients under age 65 years become Medicare eligible and have regular data reporting of data.

The USRDS previously reported the treatment modality use at two years after ESRD onset separately for diabetic and non-diabetic patients (USRDS, 1993). Here we describe the modality use after the same interval according to the early treatment modality (presumably the "modality of choice" for most cases). Patients were defined by their treatment on day 90 of ESRD either as center hemodialysis or as CAPD/CCPD. Figure V-6 shows for male and female patients the treatment modality used at two years following the designation as a hemodialysis patient on day 90 of ESRD. All patients of the age group 20 - 44 years who started therapy during 1987 to 1989 were eligible. This age group was chosen since it is the adult age group during the first year with the highest transplantation rate. At 2 years, 15 to 17 percent of patients had died, the higher number referring to males. Almost half the patients were still on

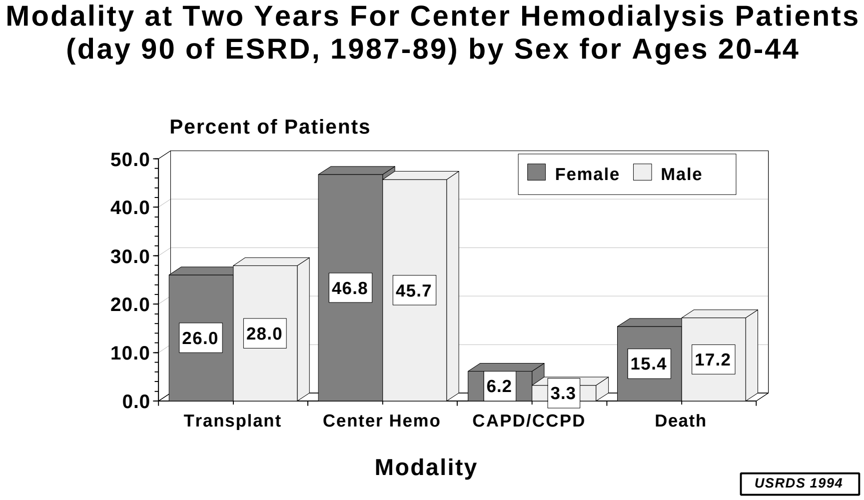



**Figure V-6**

*Modality at Two Years for Patients Receiving Center Hemodialysis at Day 90 during 1987-89, by Sex for Ages 20-44. Other and unknown modalities are not shown. Medicare patients only. Source: Reference Tables C.26, C.27.*

hemodialysis and 26-28 percent had a functioning transplant (some additional patients had likely received a transplant which had failed by the two year point). CAPD/CCPD was utilized by 3-6 percent of patients at two years. The observed sex differences are in the direction expected from the findings for prevalent patients (Table V-2).

Figure V-7 uses the same format for CAPD/CCPD patients, defined according to their treatment on day 90 of ESRD. The fraction dead and the fraction with functioning transplant are similar to that shown in Figure V-6. The

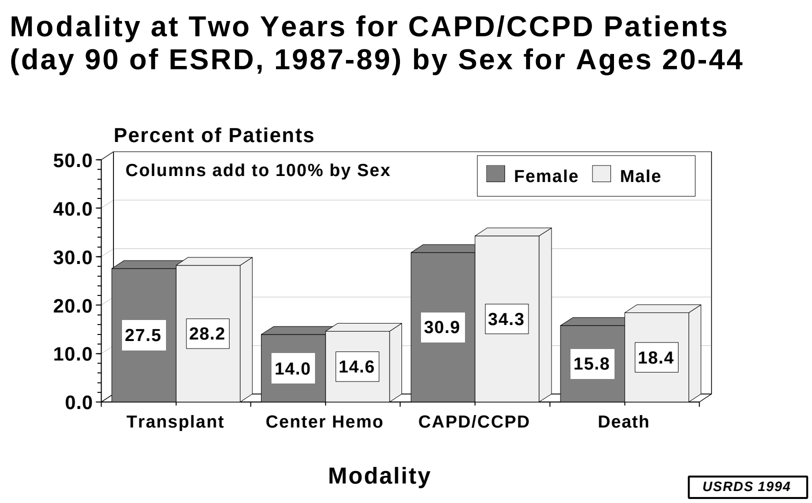



**Figure V-7**

*Modality at Two Years for Patients Receiving CAPD or CCPD at day 90 during, 1987-89, by Sex for Ages, 20-44. Other and unknown modalities are not shown. Medicare patients only. Source: Reference Tables C.26, C.27.*

**Distribution of Dialyzers in Use**
**1990-1991***

| Rank | Model | Analysis Sample** (n=2,569) Percent | Analysis Sample** (n=2,569) Cumulative(%) | Total Sample (n=4,230) Percent | Total Sample (n=4,230) Cumulative(%) |
|---|---|---|---|---|---|
| 1 | Fresenius F80 | 13.8 | 13.8 | 10.1 | 10.1 |
| 2 | NMC Focus 120 | 8.9 | 22.7 | 8.3 | 18.4 |
| 3 | Baxter CF 15-11 | 5.3 | 28.1 | 6.4 | 24.8 |
| 4 | NMC Focus 90 | 5.3 | 33.4 | 5.7 | 30.5 |
| 5 | Baxter CF 23-08 | 5.1 | 38.5 | 4.5 | 35.1 |
| 6 | Fresenius F60 | 5.1 | 43.6 | 4.2 | 39.3 |
| 7 | Baxter CA 110 | 4.8 | 48.3 | 5.2 | 44.5 |
| 8 | Terumo TAF 175 | 4.6 | 52.9 | 3.3 | 47.8 |
| 9 | Terumo TAF 12 | 4.3 | 57.2 | 3.7 | 51.5 |
| 10 | Baxter CA 210 | 4.0 | 61.2 | 3.1 | 54.6 |
| 11 | Terumo C121L | 3.4 | 64.6 | 3.4 | 58.0 |
| 12 | Terumo C101L | 3.1 | 67.7 | 3.1 | 61.2 |
| 13 | Terumo TAF 10 | 2.5 | 70.2 | 3.5 | 64.7 |
| 14 | Baxter CA 90 | 2.3 | 72.5 | 2.9 | 67.6 |
| 15 | Baxter CF 12-11 | 2.2 | 74.7 | 4.4 | 72.0 |
| 16 | Baxter CT 190 | 1.7 | 76.4 | 1.2 | 73.2 |
| 17 | Fresenius F8 | 1.5 | 77.9 | 1.4 | 74.6 |
| 18 | Terumo ICL-M151L | 1.5 | 79.4 | 1.0 | 75.6 |
| 19 | Baxter CA 170 | 1.3 | 80.7 | 1.2 | 76.9 |
| 20-113*** | All others | 19.3 | 100.0 | 23.1 | 100.0 |

* From the USRDS Case Mix Adequacy Study,1990-91
** Bicarbonate only, patients prevalent > 1 year.
*** Each 1.0% or less.

*USRDS 1994 Revised*

**Table V-3**

fraction on the original treatment of CAPD/CCPD was 31-34 percent which was over 10 percentage points lower than for the hemodialysis group remaining on the original treatment. Correspondingly, the fraction having switched to center hemodialysis was much larger at 14-14.6 percent. Thus a comparison of figures V-7 and V-6 shows that the fraction having switched from CAPD to hemodialysis is two to four fold greater than the fraction having switched from hemodialysis to CAPD.

## Dialysis Prescription for Hemodialysis

The USRDS Case Mix Adequacy Study collected information for a random sample of hemodialysis patients prevalent on January 1, 1991 and incident patients starting ESRD therapy during 1990. Preliminary analyses of these data are provided here regarding the prescribed dialysis in the U.S., excluding the small fraction of patients treated with twice weekly dialysis or with acetate dialysate. The most commonly used dialyzers are shown from this sample and for all patients in Table V-3. Fifteen dialyzers were used by 75 percent of patients. As indicated in Figure V-8, the majority of all dialyzers can be labeled as low flux (73.8 percent) according to an ultrafiltration coefficient (KUF of less than 10 ml/min/mmHg). Almost 22 percent of patients were

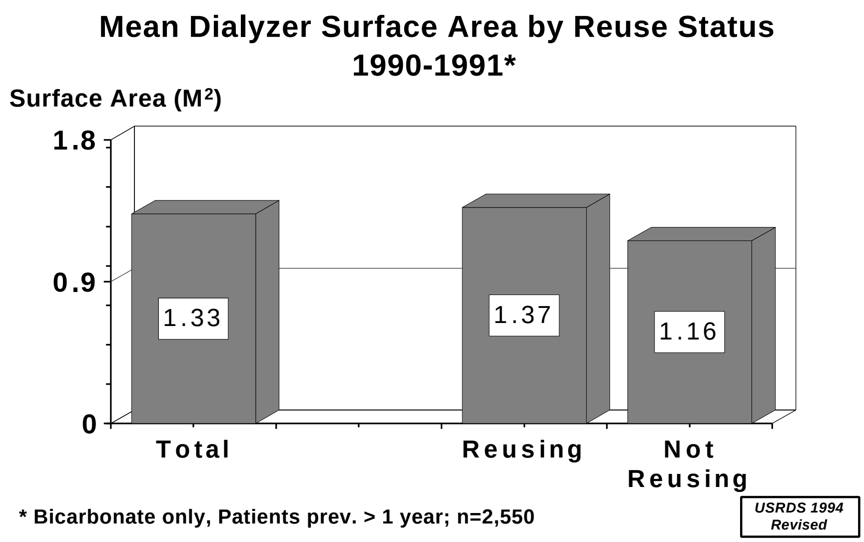



**Figure V-10**

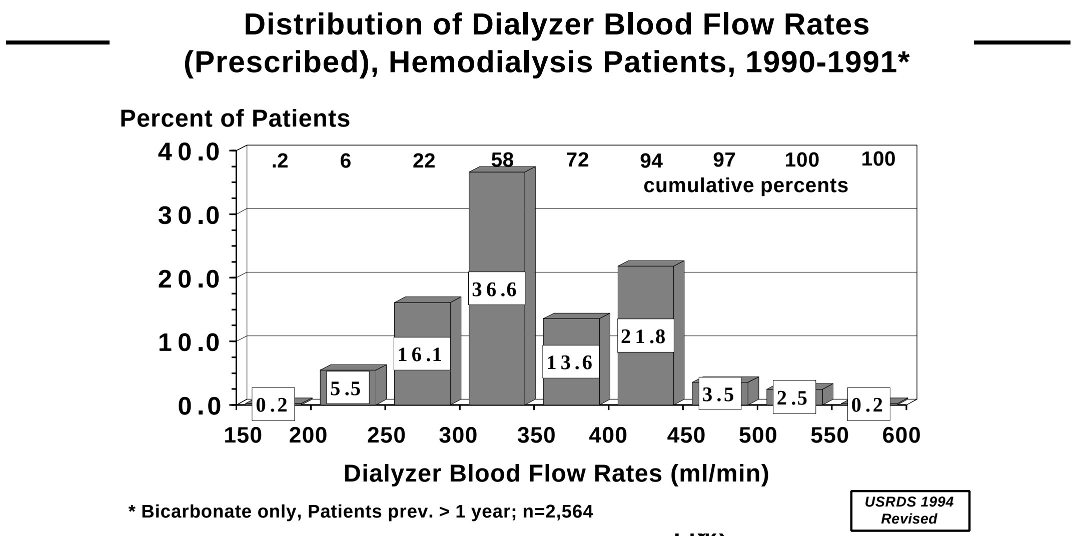
*Mean dialyzer surface area by reuse status, 1990-91. From the USRDS Case Mix Adequacy Study. Bicarbonate dialysate only, patients prevalent greater than 1 year. n = 2,550, (preliminary).*

Distribution of Dialyzer Flux (KUF)
*Distribution of dialyzer flux, by ranges of ultrafiltration coefficients (KUF), 1990-91. From the USRDS Case Mix Adequacy Study. Bicarbonate dialysate only, patients prevalent greater than 1 year. n=2,577, (preliminary).*

treated with high flux dialyzers (KUF ≥20 ml/min/mmHg).

Re-use of hemodialyzers had reached 79.4 percent in early 1991 and was more commonly employed with high flux dialysis as shown in Figure V-9. The surface area of dialyzers averaged 1.33 $m^2$. However, as Figure V-10 indicates, the surface area prescribed for re-used dialyzers was markedly larger than for dialyzers not re-used.

The prescribed dose of dialysis




* Bicarbonate only, Patients prev. > 1 year; n=2,577
USRDS 1994 Revised

**Figure V-11**

*Distribution of dialyzer blood flow rates, including cumulative percentages, 1990-91. From the USRDS Case Mix Adequacy Study. Bicarbonate dialysate only, patients prevalent greater than 1 year. n = 2,564, (preliminary).*

**Figure V-9**
*Percent of patients reusing dialyzers by flux level, 1990-91. From the USRDS Case Mix Adequacy Study. Bicarbonate dialysate only, patients prevalent greater than 1 year. n = 2,577, (preliminary).*

depends also on blood flow rates. The prescribed blood flow rate averaged 327 ml/min and its distribution is shown in Figure V-11. The prescribed treatment times for patients on a thrice weekly schedule were less than three hours in 17 percent of patients and hardly any patients had more than 4.5 hours prescribed as shown in figure V-12.

Although the prescription of dialysis is important, it has been well recognized that patients receive on average a lower dialysis dose than prescribed. The delivered dose of dialysis can be estimated from pre and post dialysis blood urea concentrations and body weights.

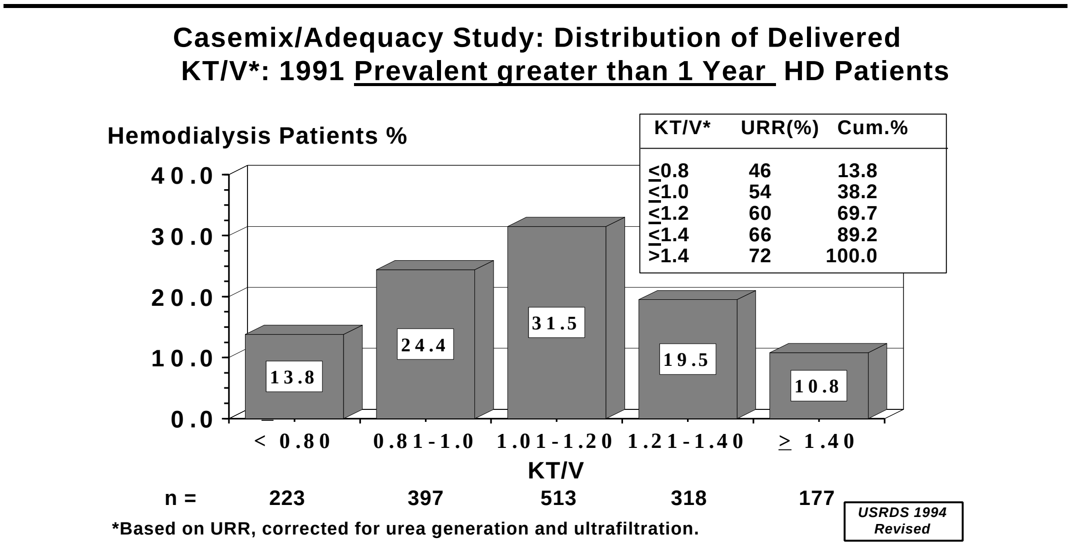
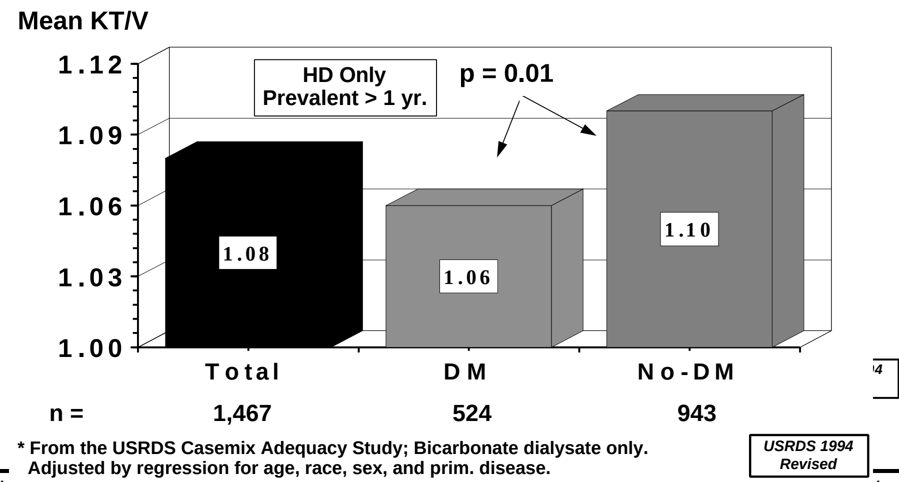



**Figure V-13**

*Distribution of delivered dose of dialysis , 1990-91, based on (URR) urea reduction ration,, corrected for urea generation and ultrafiltration as KT/V (J Daugirdas, JASN, Oct 1992). From the USRDS Case Mix Adequacy Study. Patients prevalent greater than one year. n = 1,628 (preliminary).*

**Distribution of Hemodialysis Treatment Times**

**Delivered KT/V by Diabetic Status, 1990-91***




*Distribution of prescribed treatment times for hemodialysis patients treated thrice weekly, including cumulative percentages, 1990-91. From the USRDS Case Mix Adequacy Study. Bicarbonate dialysate only, patients prevalent greater than 1 year. n = 2,406 (preliminary).*

**Figure V-14**

*Delivered KT/V by Diabetic Status, 1990-91. From the USRDS Casemix Adequacy Study. Hemodialysis patients only, patients prevalent greater than one year, bicarbonate dialysate only. Adjusted by regression for age, race, sex, and primary disease.*

To calculate the dose of KT/V from these data for patients on thrice weekly dialysis, the formula published by Daugirdas (1992) was used. Since residual renal function may provide a significant portion to the total clearance during the first several months of ESRD, we elected to include only patients who had been on dialysis for at least one year. Among these patients on thrice weekly dialysis, the delivered KT/V ranges are shown in Figure V-13. Thirty eight percent of patients received delivered KT/V of 1.0 or less, which is lower than recommended by the National Cooperative Dialysis Study (Gotch) and the Consensus Conference (1994). A high dose of dialysis of over 1.4 KT/V was received by 10.8 percent of patients.

To determine whether the delivered dose of dialysis varied by diabetic status, delivered KT/V was assessed from preliminary Case Mix/Adequacy Study data for patients with and without diabetes as the cause of ESRD.

As shown in Figure V-14, patients with diabetic ESRD received a 4 percent lower dose of dialysis than patients with other causes. This analysis excluded patients whose ESRD started less than one year earlier (to limit the role of unmeasured residual renal function) and was adjusted for age, sex, race and cause of ESRD.

## Dialysis Prescription for CAPD

Since the recent Case Mix Adequacy sample did not include CAPD patients, the prescribed dose of CAPD was available to the USRDS only from the incident patient sample of the 1986-87 Case Mix Severity Study. In that sample of approximately 634 patients, 68 percent of patients had a prescription of 55 to 60 liters per week (mostly four 2-liter exchanges per day). Only 4 percent

**Percent of Medicare Dialysis Patients Receiving Epo by Quarter, 1989-1992**

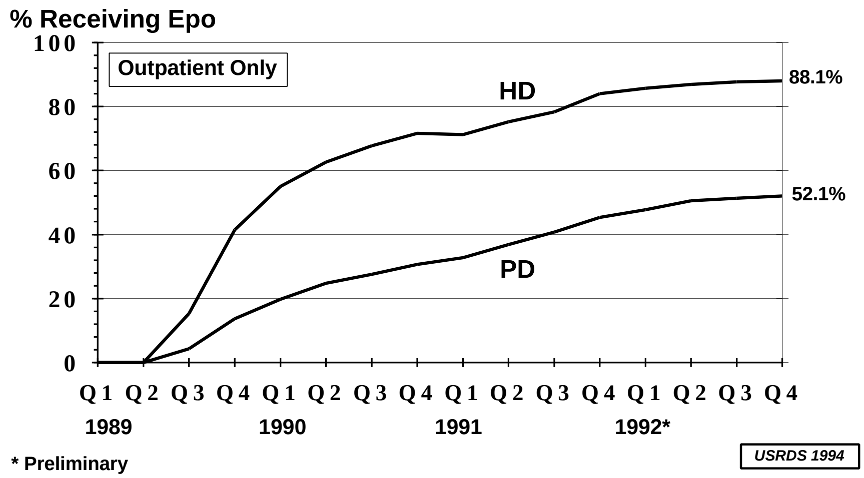



**Figure V-15**

*Percent of Medicare Dialysis Patients Receiving Epo as outpatients by Quarter, 1989-1992. Patients changing modalities during a quarter are not shown. From the Quarterly Dialysis Records which reports data from outpatient institutions only, i.e. physician offices are excluded. (See Technical notes, Chapter XV, for details of the Quarterly Dialysis Records File.)*

of patients used larger weekly volumes. A lower weekly dialysate volume was prescribed in 27 percent of patients (USRDS 1992). These data suggest that a low dose of CAPD is prescribed to a large fraction of patients at the start of ESRD. Unless the prescription is increased when residual renal function declines, this would be judged an inadequate dose by most authorities. Hardly any data are presently available on the actually delivered volumes of dialysate in CAPD patients. There is concern that lack of compliance to this form of home dialysis may explain in part the outcomes compared to hemodialysis (Chapters VI and VII).

## Erythropoietin Use in Dialysis Patients

The utilization of recombinant human erythropoietin (EPO) has markedly increased since its introduction in the U.S. and coverage by Medicare in July 1989. As shown in Figure V-15, the fraction of outpatients receiving EPO increased most dramatically during the first year (1989/90) for those covered by Medicare and treated with either hemodialysis and peritoneal dialysis. This fraction reached 88.1 percent by the end of 1992 for hemodialysis patients and remained consistently lower in peritoneal dialysis patients, reaching 52.1 percent by late 1992.

Hemodialysis patients with diabetic ESRD were more likely to be treated with EPO than non-diabetics (Figure V-16) for ages less than 65 years, while the trend was in the opposite direction for geriatric ages. Overall, the fraction of patients receiving EPO increased with age.

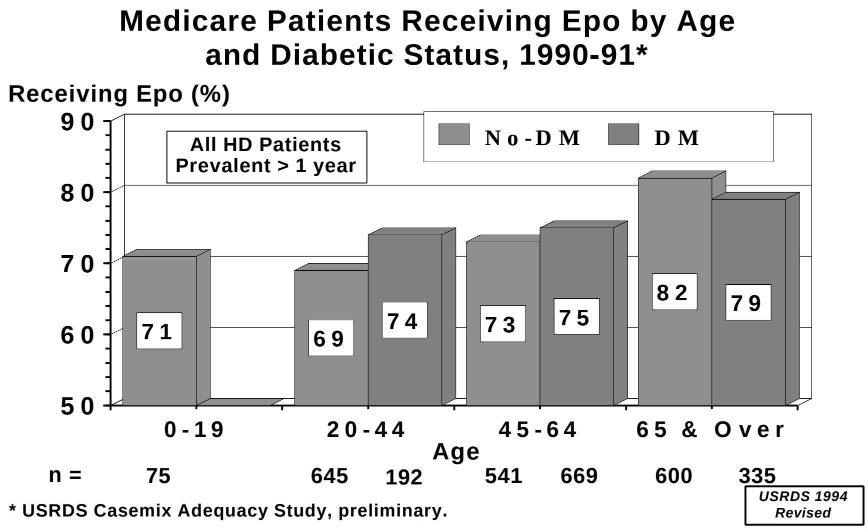



**Figure V-16**

*Medicare Patients Receiving EPO by Age and Diabetic Status, 1990-91. From the USRDS Casemix Adequacy Study. Hemodialysis patients only, prevalent greater than one year.*

Data from the USRDS Case Mix Adequacy Study allow a preliminary assessment of hematocrit levels among patients receiving EPO and those not receiving EPO. For patients treated by hemodialysis for over one year, Figure V-17 shows that hematocrit levels were lower among patients treated with EPO, suggesting that EPO is used primarily in patients with significant anemia. Patients with diabetic ESRD have similar hematocrits as patients with other causes of ESRD in both EPO treated and untreated groups.

At the start of ESRD therapy the trend in the level of anemia can be described from the USRDS Case Mix Severity Study of 1986-87 and Case Mix Adequacy Study of incident patients in 1990. Figure V-18 shows that hematocrit levels were higher in the more recent year for each race and sex group. Whereas females had slightly lower levels than males in 1986-87, no such differences could be detected in 1990. The hematocrit tended to be lower for blacks and other races than for whites, particularly in the earlier period. The issue of access to EPO therapy by race was addressed recently by Petronis (1994).

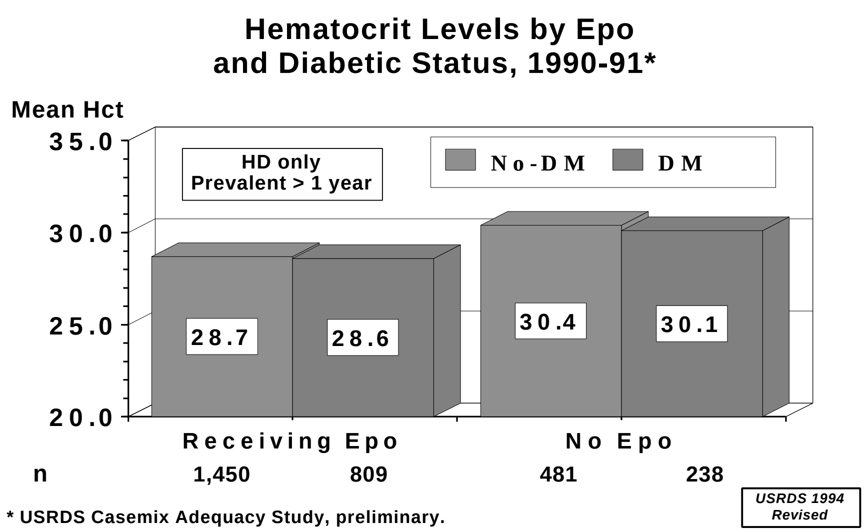



**Figure V-17**

*Hematocrit Levels by EPO and Diabetic Status, 1990-91. From the USRDS Casemix Adequacy Study. Hemodialysis patients only, prevalent greater than one year.*

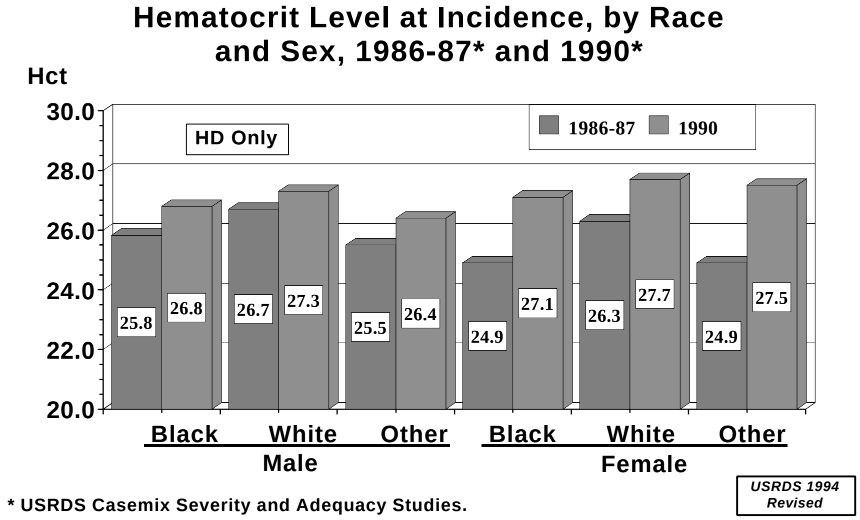



**Figure V-18**

*Hematocrit Level at Incidence, by Race and Sex, 1986-87 and 1990. From the USRDS Casemix Severity and Adequacy Studies, hemodialysis patients only.*

The finding of a lower hematocrit among patients treated with EPO compared to untreated patients was confirmed for all adult age groups but not for pediatric ages as shown in figure V-19. The relatively high hematocrit levels among untreated patients suggest that the 20 to 30 percent of patients not receiving EPO (Figure V-16) have on average a less severe anemia.

Benefits of EPO therapy can be measured in several ways including changes in hematocrit levels and blood transfusions. Figure V-20 shows the fraction of patients receiving any blood transfusion by quarter for 1989 through 1992. Following the introduction of EPO in July 1989, there has been a clear reduction in the fraction of hemodialysis patients transfused, i.e. from 16 percent to 3 to 4 percent.

For patients receiving EPO, the hematocrit is reported to HCFA on a billing period basis, typically a month. Figure V-21 shows the average hematocrit and the average ($\bar{X}$) and median dose (M) of EPO by quarter for 1989 through 1992. The dates for EPO introduction and change in payment from a per administration to a per dose basis (January 1991) are indicated in this figure. The EPO dose showed an increase since the fall of 1990. The most recent average dose was still below that used in phase III clinical trials (Eschbach). The difference between the mean and the median dose in figure V-21 is likely due to outlier values of high doses. Since the frequency of administration may have changed over time, a better measure of the actual dose would be per week or per month.

**Hematocrit Levels For All Hemodialysis Patients by Age and Epo Status, 1990-91***

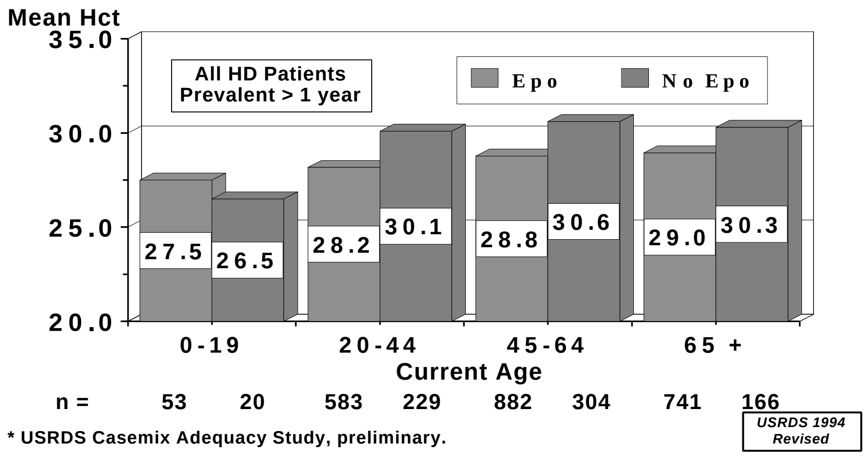



**Figure V-19**

*Hematocrit Levels For All Hemodialysis Patients by Age and EPO Status, 1990-91. From the USRDS Casemix Adequacy Study. Hemodialysis patients only, prevalent greater than one year*

The hematocrit level increased on average by 2.5 percentage points overall and by 0.7 percentage points during 1991 and 1992. Parenteral iron therapy may reduce the EPO dose requirement in some patients (Van Wyck) and is necessary for patients not tolerating oral iron. Therefore, the unavailability of parenteral iron during 1991 and the first half of 1992 is also indicated in Figure V-21.

**Hemodialysis Patients Receiving Outpatient Blood Transfusions by Quarter, 1989-1992**

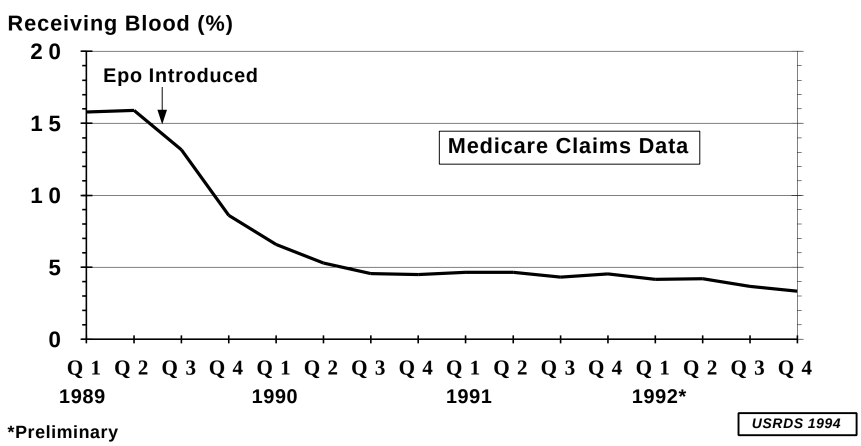



**Figure V-20**

*Hemodialysis Patients Receiving One or More Outpatient Blood Transfusions by Quarter, 1989-92. From the Quarterly Dialysis Records (See Technical notes, Chapter XV, for details of the Quarterly Dialysis Records File.)*

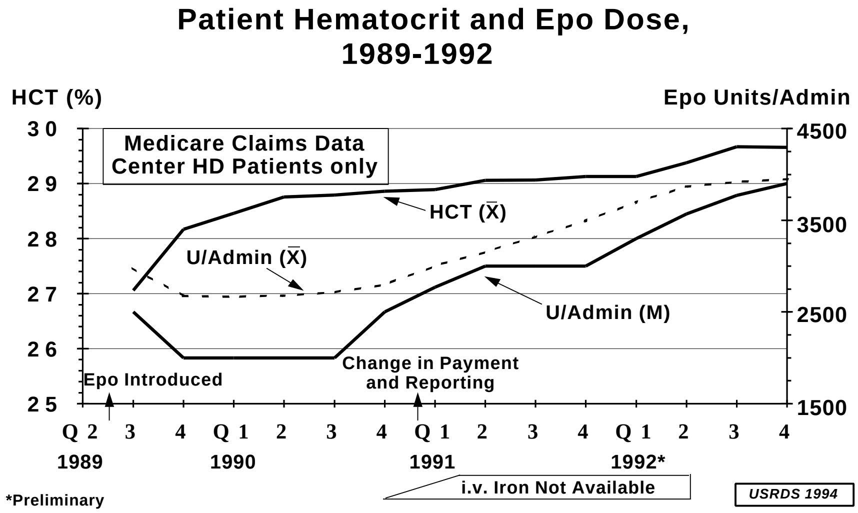



**Figure V-21**

*Average Patient Hematocrit and EPO Dose by Quarter, 1989-1992. X-Bar is the mean. M is the median. U is EPO units. Admin. is administration Center hemodialysis patients only. Before 1/1/91, EPO dose was reported as the last dose in the billing period. After 1/1/91, reported dose was calculated by HCFA as the average over the billing period. From the Quarterly Dialysis Records (See Technical notes, Chapter XV, for details of the Quarterly Dialysis Records File.)*

Several additional factors may influence the magnitude of the rise in hematocrit in addition to the weekly dose of EPO, including the characteristics of the patients entering the treated pool, the adequacy of the delivered dialysis dose, blood loss during dialysis and other factors.

## Vascular Access

Vascular access complications are among the most common indications for

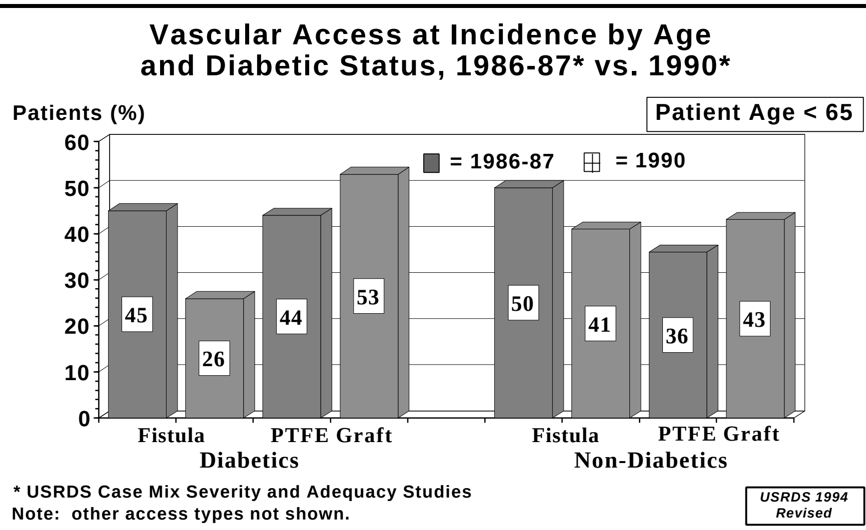



**Figure V-22**

*Vascular Access by Age and Diabetic Status, 1986-7 vs. 1990. From the USRDS Casemix Severity and Adequacy Studies. Hemodialysis patients only, age less than 65.*

hospitalization among hemodialysis patients and add substantially to the cost of ESRD therapy. The USRDS Case Mix Studies collected information about the type of vascular access used at the start of ESRD therapy in 1986/87 and 1990. The arterio-venous fistula (Brescia-Cimino shunt) and the synthetic PTFE vascular graft (polytetrafluroethylene) account for over 75 percent of initial vascular accesses. As shown in Figure V-22, patients with diabetic ESRD were more likely to use a PTFE graft than those with other causes of ESRD. A comparison between the earlier and later incidence years of study reveals that the fraction with AV fistula decreased by 9 to 19 percentage points, while the fraction with PTFE graft increased by 7 to 9 percent over time. These patterns by diabetes and over time are shown for patients under the age of 65 years but they were very similar for older patients. The impact of these new trends on vascular access complications deserves future studies.

## References and End Notes:

Braun WE. Long-term complications of renal transplantation. Kidney Int 1990; 37:1363-1378.

Daugirdas JT. The pre:post dialysis plasma urea nitrogen ratio to estimate Kt/V and NPCR: Mathematical modeling. Int J Artif Organs 1989; 12:411-419.

Erslev A. Erythropoietin coming of age. N Engl J Med 1987; 316:101-123.

Evans RW, Blagg CR, Bryan FA. A social and demographic profile of hemodialysis patients in the United States. JAMA 1981; 245:491.

Evans RW, Manninen DL, Garrison LP, Jr., Hart LG, Blagg CR, Gutman RA, Hull AR, Lowrie EG. The quality of life of patients with end-stage renal disease. N Engl J Med 1985; 312:553-559.

Fox RC, Swazey JP. The Courage to Fail: A Social View of Organ Transplants and Dialysis. 2d rev. ed. Chicago: University of Chicago Press, 1979.

Gaylin DS, Held PJ, Port FK, Hunsicker LG, Wolfe RA, Kahan BD, Jones CA, Agodoa LYC. The impact of comorbid factors on access to renal transplantation. JAMA 1993; 269:603-608.

Gotch FA, Sargent JA. A mechanistic analysis of the National Cooperative Dialysis Study. Kidney Int 1985; 28:526-534.

Hamilton D. Kidney transplantation: a history. In: Morris PJ, ed. Kidney Transplantation: Principles and Practice. Grune and Stratton, London, 1984.

Health Care Financing Administration. Proposed rule: prospective reimbursement for dialysis services. Fed Reg 1982; 42:6556-6575.

Held PJ, Pauly MV, Bovbjerg RR, Newmann JM, Salvatierra O, Jr. Access to kidney transplantation: Has the United States eliminated income and racial differences? Arch Intern Med 1988; 148:2594-2600.

Iwaki Y, Cecka JM, Terasaki PI. The transfusion effect in cadaver kidney transplants—yes or no? Transplantation 1990; 49:56-59.

Kahan BD, Van Curen CT, Flechner SM, Jarowenko M, Yasumura T, Rogers AJ, Yoshimura N, LeGrue S, Drath D, Kerman RH. Clinical and experimental studies with cyclosporine in renal transplantation. Surgery 1985; 97:125-131.

Kramer P, Broyer M, Brunner FP, Brynger H, Challah S, Oules R, Rizzoni G, Selwood NH, Wing AJ, Balas EA. Combined report on regular dialysis and transplantation in Europe, XIV, 1983. Proc EDTA-ERA 1984; 21:5-65.

Merion RM, White DJG, Thiru S, Evans DB, Calne RY. Cyclosporine: five years' experience in cadaveric renal transplantation. N Engl J Med 1984; 310:148-154.

Murray JE, Merrill JP, Harrison, JH. Renal homotransplantation in identical twins. Surg Forum 1955; 6:432-435.

National Institutes of Health: Morbidity and Mortality in Dialysis. NIH Consensus Statement 1993; 11(2):1-33.

Opelz G for the Collaborative Transplant Study. HLA matching and transplant survival: effect of HLA matching in 10,000 cyclosporine-treated cadaver kidney transplants. Transpl Proc 1987; 19:641-646.

Peters PC. Dialysis and transplantation: the past. Semin Nephrol 1982; 2:79-89.

Petronis KR, Carroll CE, Held PJ, Port FK. Effect of race on access to recombinant human erythropoietin in long-term hemodialysis patients. JAMA 1994; 271: 1760-1763.

Prottas JM. Shifting responsibilities in organ procurement: a plan for routine referral. JAMA 1988; 260:832-833.

Rettig RA. The Federal government and social planning for end-stage renal disease: past, present, and future. Semin Nephrol 1982; 2:111-133.

Rettig RA, Levinsky RA (eds): Kidney Failure and the Federal Government, National Academy Press, Washington DC, 1991.

Sheil AGR. The second international congress on cyclosporine. Transpl Proc 1988; 20(suppl 3):1123-1331.

Twardowski ZJ. Peritoneal dialysis: glossary III. Perit Dial Int 1990; 10:173-175.

United States Renal Data System. Characteristics of dialysis prescription in the U.S., 1986-87. Am J Kidney Dis 1992; 20(Suppl.2):39-47.40-6

United States Renal Data System. Patient selection to peritoneal dialysis versus hemodialysis according to comorbid conditions. Am J Kidney Dis 1992; 20(Suppl.2): 20-26.

United States Renal Data System. USRDS 1991 Annual Data Report. National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases. Bethesda, MD, 1991.

United States Renal Data System. USRDS 1993 Annual Data Report. National Institutes of Heath, National Institute of Diabetes and Digestive and Kidney Diseases. Bethesda, MD. 1993.

Van Wyck DB, Stivelman JC, Ruiz J, Kirlin LF, Katz MA, Ogden DA. Iron status in patients receiving erythropoietin for dialysis-associated anemia. Kidney Int 1989; 35:712-716.

Webb RL, Port FK, Gaylin DS, Agodoa LY, Greer J, Blagg CR. Recent trends in cadaveric renal transplantation. In: Terasaki PI, ed. Clinical Transplants 1990. UCLA Tissue Typing Laboratory, Los Angeles, 1991: 75-87.

End note: Several analyses in this chapter compared data from the 1986/87 Case Mix / Severity Study with corresponding data from 1990 incident patients of the Case Mix / Adequacy Study. These analyses had to be adjusted for the fact that incident patients of 1990 had to be alive and on in-center hemodialysis on December 31, 1990 in order to be selected for study. Therefore, the same rule was applied for the 1986/87 sample. i.e. incident patients of 1986 or 1987 who died or changed modality before the end of the incidence calendar year were excluded from these comparative analyses. This revised methodology was used in figures V-18 and V-22.