# Chapter III

# Treatment Modalities for ESRD Patients

*Key Words*:
CAPD
CCPD
Dialysis dose
Dialyzer membrane
ESRD modality
Hemodialysis
Home hemodialysis
Peritoneal dialysis
Transplant, renal

The modalities of renal replacement therapy available for the treatment of end-stage renal disease (ESRD) include renal transplantation, hemodialysis, and peritoneal dialysis. Hemodialysis (HD) is subdivided in this chapter into center HD, the most commonly used modality, and home HD. Peritoneal dialysis (PD) comprises both continuous ambulatory PD (CAPD), and continuous cycling PD (CCPD), in addition to a small subgroup of other forms of PD. Renal transplantation may be from a living donor (either a blood relative or other emotionally related donor) or a cadaveric donor. Transplantation is discussed in more detail in Chapter VII. During the course of being treated for ESRD, patients may switch a number of times between the different modalities of renal replacement therapy. For example, a given patient might move from CAPD to transplantation and, after transplant failure, to hemodialysis and perhaps to a second transplant.

Based on data reported for all covered ESRD patients in the United States, the following sections will review the different treatment options available; discuss trends in the use of different modalities over time; and examine demographic differences in the patterns of modality utilization in 1997. In addition, the USRDS Special Studies and/or Health Care Financing Administration's ESRD Core Indicators Report provide data, on national, random samples of ESRD patients, and allow for descriptions of further trends over time: in delivered dialysis dose for HD and PD; in patterns of dialysis membrane utilization in hemodialysis; and in average hematocrit levels for HD patients.

## Treatment Modality Options

### An Abbreviated History

During the 1960s hemodialysis, peritoneal dialysis and renal transplantation became a reality for ESRD patients (Peters). Prior to 1960, dialytic modalities as temporary treatment were saving some patients with acute renal failure. A few identical-twin living donor transplants had been successfully performed, but no treatment other than dietary modification was available for patients with chronic renal failure reaching ESRD. Then, beginning in 1960 with Belding Scribner's work, the first patients were treated with hemodialysis for *chronic* renal failure. The chronic use of peritoneal dialysis followed the development, during the 1960s, of the soft cuffed Tenckhoff catheter. Renal transplantation from nonidentical twins also became a reality during the 1960s, through improved understanding of immunology and through the use of immunosuppressive therapies.

Congress enacted Medicare coverage for end-stage renal disease as part of the Social Security Amendments of 1972, which became effective in July 1973 (Fox; Rettig 1982). Several legislative changes in Medicare's ESRD program have sought to encourage reduction in treatment costs through shifts in modality to home dialysis and changes in payment

methods (HCFA). A report from the Institute of Medicine discusses the potential impact of reductions in the reimbursement rate (actual as well as due to inflation) for dialysis treatments (Rettig, 1991). Some additions to coverage have also been made, notably outpatient erythropoietin therapy for the anemia of dialysis patients and an increase (for up to 3 years) for immunosuppressive drugs after transplantation.

## Description of Options

Over 300,000 ESRD patients are currently alive in the United States as a result of ESRD therapy, compared to an estimated 11,000 patients in 1973 (Evans, 1981). Quality of life for ESRD patients varies widely. However, even after accounting for the benefits of EPO therapy, quality of life instruments show that ESRD patients, when compared to the general population, have on average substantially lower scores across most dimensions of functional health and well-being, excepting mental health (Beusterien, 1996).

**Renal transplantation:** Renal transplantation from living-related and cadaveric donors became a clinical reality during the 1960s (Hamilton). Surgical technique had been well developed before this time, but advances in the understanding and pharmacologic manipulation of the immune response made transplantation from nonidentical donors possible. Tissue typing came into routine use during the 1960s, as did the pretransplant lymphocyte cross-match between donor cells and recipient serum. More recently, improved immunosuppression with cyclosporine, tacrolimus (FK-506), and other newer agents has further expanded treatment prospects and graft survival (Merion, Kahan, and Wagner). However, because of the limited availability of donor organs, cadaveric transplantation has shown only a minor growth in the United States since 1986 (Prottas; Chapter VII).

Living donors are predominantly blood relatives, although there has been an increase in recent years in genetically unrelated kidney donations from, for example, a recipient's friend or domestic partner. A cadaver donor is a person who is brain dead but who is maintained on artificial life support, such as an accident victim. The average waiting time to receive a transplant from a cadaver donor is long, typically greater than 2 years, and it continues to increase. In contrast transplantation from a living donor can be scheduled electively and is more likely to be an early, or even to be the initial, ("preemptive") modality of renal replacement therapy. Survival of the transplanted kidney (graft or allograft) is influenced by a variety of factors (Opelz, Held 1994a; Braun) including: HLA matching; duration of organ preservation (warm and cold ischemia time) following removal of the organ, presence or absence of panel reactive antibodies, patient and donor demographic factors, rejection episodes, and immunosuppressive drug regimens. These factors are described further in Chapter VII.

**Hemodialysis:** Hemodialysis removes toxins and excess fluid via extracorporeal circulation of blood through a dialyzer, or so-called "artificial kidney". Treatments are most commonly scheduled three times weekly and last 3 to 4 hours. A vascular access is required, using an arterio-venous (AV) fistula, vascular graft, or indwelling vascular catheter. The treatment is performed predominantly as "center hemodialysis" in a hospital-based or freestanding dialysis unit. In this setting patients' dialyzers are commonly reprocessed. Thus, a given patient may reuse his/her dialyzer multiple times.

Hemodialysis may be performed at home as "home hemodialysis" after the patient and an assistant (often the spouse) undergo several weeks of training. Home hemodialysis encourages patient independence and allows freedom to schedule dialysis to meet patient convenience. Those treated with home hemodialysis seem to enjoy a better quality of life (Evans 1985) and are reported to have better survival (Woods) compared to center hemodialysis. Recently, home hemodialysis has been performed as a daily treatment given as either short daytime (Buoncristiani) or slow nighttime dialysis (Pierratos).

**Peritoneal dialysis:** PD uses the peritoneal membrane as an alternative surface for dialysis. It requires placement of a catheter into the abdominal cavity, and repeated instillation and drainage of sterile dialysate. Because of concentration gradients, toxins move from the plasma to the dialysate during the dwell time. Dwell times vary from several hours in CAPD, to 1 hour or even shorter in other forms of cyclic PD. Toxins, having partly or almost fully equilibrated with the dialysate, are removed when the dialysate is drained. Fluid is removed through osmotic ultrafiltration by use of hypertonic dialysate solutions.

Several peritoneal dialysis options are available. The most common is continuous ambulatory PD (CAPD). The patient usually performs four or five exchanges with a dialysate volume of 2-3 liters on a daily basis. Continuous cycling PD (CCPD), also

predominantly a home treatment, utilizes several exchanges through a programmed machine (cycler), typically every night, with one long dwell time throughout the day. The utilization of CCPD has increased in recent years, accounting for 15 percent of PD use in 1995 and over 36 percent in 1997 (USRDS 1997). Combinations of CAPD and CCPD have recently been utilized, particularly in large patients with no residual renal function (Diaz-Buxo). Intermittent PD (IPD) has exchanges of dialysate three to seven times weekly for 8 to 12 hours and is performed with the cycler (also an automated PD). However, with IPD the abdomen is empty when disconnected from the cycler. Several other variations of home PD have been described (Twardowski), but are not uniformly recorded and thus are not discussed further in this report.

CAPD and CCPD are used frequently for patients who prefer the independence of self-care and for those who have difficulty with vascular access or other aspects of hemodialysis. Thus, there may be two extreme groups of patients who are selected for PD: those who are stable and independent and those who are unstable and poorly tolerant of hemodialysis. Comorbid conditions at the initiation of PD and HD have been described by the USRDS for a random sample of patients (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 that switches to CAPD (see Reference Table C.9). Recurrent peritonitis may be in part responsible for this observation. One may also speculate that, as residual renal function is lost, lower total weekly clearances could prompt some switching from CAPD to hemodialysis.

## Data for Modality Analyses

To determine the sequential changes in treatment modalities for individual patients, the USRDS uses a complex analytical process, examining a variety of data sources. In addition to the main database, the facility surveys of the ESRD Networks and HCFA billing data are used. The actual process is described in greater detail in Chapter XIII. For many cases, treatment modality and dates of change in modality must be inferred indirectly from sources such as the Medicare payment files. Because the USRDS is continually refining this process, slight variations between the modality data reported in different Annual Data Reports should be expected.

## Trends in Modality Utilization

The treatment modality in use for all prevalent ESRD patients on December 31 of each year is determined from the USRDS longitudinal patient treatment files ("database") and from the year-end

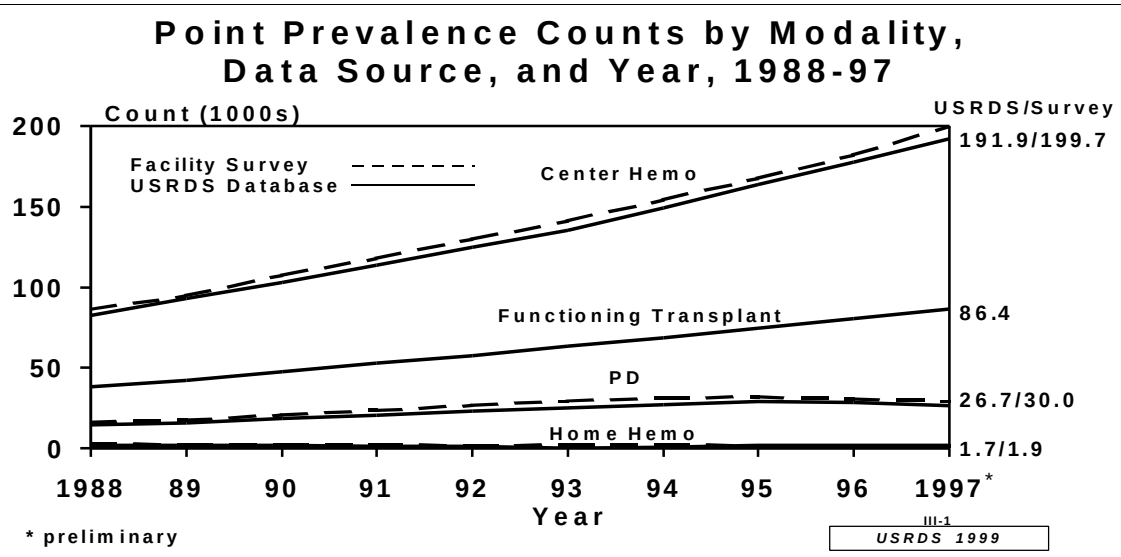


**Figure III-1**

*Point prevalence counts of ESRD patients by treatment modality, data source, and year, 1988-1997. Percentages include Puerto Rico and U.S. Territories. Source: Reference Tables C.1 and I.12.*

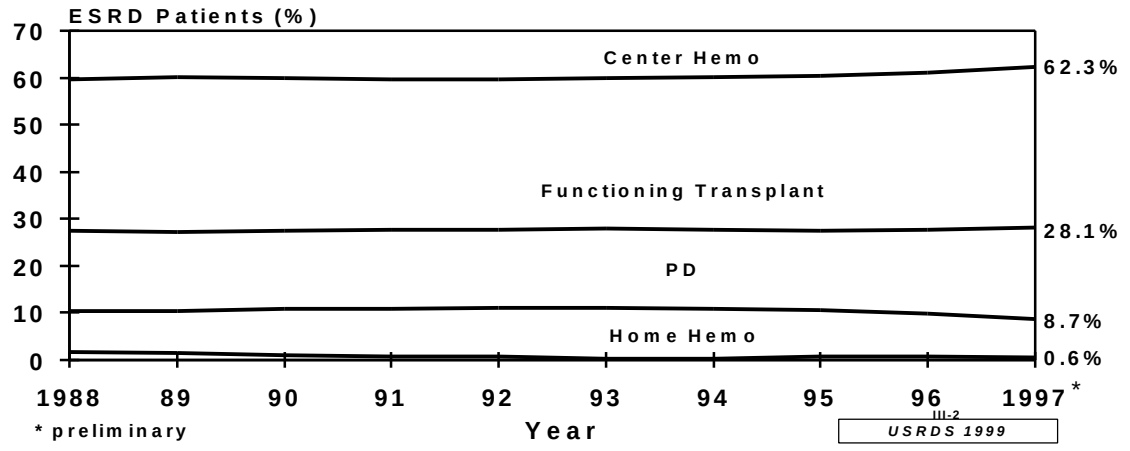


**Figure III-2**

*Percent distribution of prevalent ESRD patients, by treatment modality and year, 1988-1997. Percentages include Puerto Rico and U.S. Territories. Source: Reference Table C.1.*

Facility Survey of all Medicare-approved dialysis units. Figure III-1 shows these counts for 10 years, 1988-97. Prevalence estimates for the most recent year may be under-representative because of somewhat incomplete data (see Chapter II). About 93 percent of all ESRD patients are insured by Medicare.

The Facility Survey provides a more complete accounting of non-Medicare patients than does the USRDS database. As a result these counts of the year-end point prevalence are slightly higher than counts from the USRDS database. Transplant recipients who lost their transplant function and returned to dialysis, and those who moved from one dialysis modality to another, are shown in the appropriate dialysis group in the year-end point prevalence counts.

Over the past decade, the overall number of patients receiving renal replacement therapy for ESRD has increased steadily. This is especially apparent from the increasing year-end point prevalence counts of patients in each of the two major treatment modality categories (center HD and functioning transplant) in Figure III-1. Throughout the period, patients treated with center hemodialysis constituted the largest group and patients with a functioning renal transplant were the second largest group. Respectively, there were in excess of 191,000 (HD) and 86,000 (functioning transplant) prevalent patients treated with these two modalities alone, on December 31, 1997. Peritoneal dialysis, mostly CAPD and CCPD, has been the third most common form of ESRD therapy over the last decade. During the early 1980s, the use of PD showed a relatively steep increase (see earlier USRDS ADRs). However the year-end point prevalence counts for patients treated by PD appeared to level off in 1996 and a small decrease is noticeable in the number of patients receiving this treatment modality on December 31, 1997. The home HD patient group has continued throughout the last decade to be relatively small and shows little change in recent years.

Figure III-2 shows trends in the distribution of point prevalent ESRD patients, by treatment modality and by year, from 1988 through 1997. Before the mid-1980s, the fraction of ESRD patients on center hemodialysis had decreased relative to other modalities (see earlier USRDS ADRs). Since 1988 the percent distribution of prevalent ESRD patients by all treatment modalities has appeared remarkably stable, suggesting similar fractional growth for each modality. The fraction of patients with a functioning renal transplant increased during the 1980s prior to 1988. This was due to both a rise in the number of transplants performed and improvements in graft survival (see Chapter VII). The relatively constant percentage of ESRD patients with a functioning allograft since 1988 at least in part reflects the scarcity of available organ donors. The fraction of all

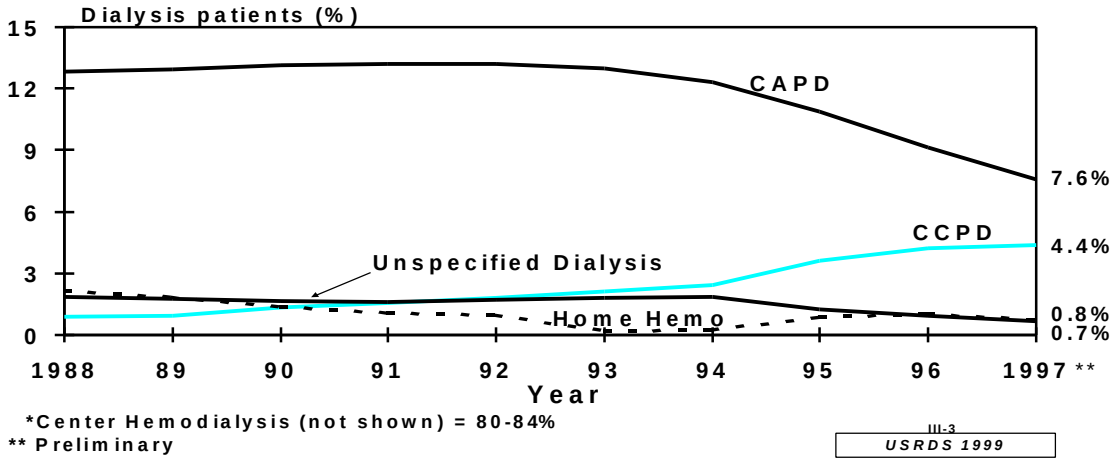


**Figure III-3**

*Percent distribution of prevalent dialysis patients, by treatment modality and year, 1988-1997. Center hemodialysis not shown. Unspecified dialysis includes other peritoneal dialysis and uncertain dialysis. Percentages include Puerto Rico and U.S. Territories. Source: Reference Table C.1.*

ESRD patients treated with peritoneal dialysis had been fairly constant since the mid 1980s but appears to have fallen from just over 11 percent in 1993 to 8.66 percent in 1997. This is consistent with the observation that the total number of year-end prevalent PD patients did not rise after 1995 and may be slightly decreased on December 31, 1997 (Figure III-1). The group of patients utilizing home hemodialysis has continued to represent only a small percentage of all ESRD patients, perhaps with a minor increase after 1994.

There were 0.5 to 3 percent of patients for whom the modality could not be determined from available data or whose modality was changing at year-end. Their data are not included in Figure III-2. Additionally, patients who initiated dialysis therapy during the last 2 months of the most recent year, 1997, are also automatically placed in this category according to definitions outlined in Chapter XIII. Excepting these patients essentially all prevalent patients are accounted for in this analysis.

Figure III-3 shows the distribution of patients on home HD, CCPD, CAPD and unspecified dialysis modalities as a percentage of all *dialysis-dependent* ESRD patients. When the percentage contribution of center hemodialysis (not shown) is added to the percentages in this figure, the numbers add to 100 percent of all dialysis patients (note the difference from Figure III-2, which indicates percentages of all ESRD patients, including patients with functioning transplants). The use of CCPD has being increasing throughout the years from 1988 to 1997. The increase in the proportion of dialysis patients managed on CCPD showed a particularly steep increase in 1995 and 1996, and a smaller percentage rise in 1997. As of December 1997, CCPD accounted for approximately 4.4 percent of all dialysis and approximately 37 percent (4.36/11.93) of the peritoneal dialysis patient population. The fraction treated by CAPD has shown a sharp decrease since 1993. This occurred partly in favor of CCPD. However, since the total fraction of dialysis patients treated with PD has also declined, from 15 percent at year-end in 1993 to approximately 12 percent at year-end 1997, some of the fractional decline in CAPD usage has also been in favor of HD. Intermittent peritoneal dialysis (IPD) has been declining and is rarely used. Patients treated with other PD or unknown or uncertain dialysis accounted for only 0.69 percent of all dialysis patients at the end of 1997.

In Table III-1 the regional differences in the utilization of various treatment modalities are described as the percent distribution of patients by modality and by Network, for each of the 18 ESRD Networks. Percentages in the dialysis modality columns are calculated from the point prevalence data

## Living Patients on December 31 By Treatment Modality, By Network 1995 Through 1997

| Network Number (State) | Total Count[a] | Median Age[a] | Functioning Transplant (%) Age 0-64 only[a] | Dialysis Modality (%)[b] Center Hemo | Home Hemo | CAPD | CCPD | Other PD/ Unknown |
|---|---|---|---|---|---|---|---|---|
| 1 (CT,MA,ME,NH,RI,VT) | 12,844 | 58.9 | 47.9 | 82.4 | 0.7 | 9.8 | 6.2 | 0.9 |
| 2 (NY) | 21,206 | 57.7 | 32.9 | 85.7 | 0.7 | 9.5 | 3.0 | 1.1 |
| 3 (NJ, Puerto Rico, Virgin Isl.) | 13,337 | 57.9 | 30.4 | 81.4 | 0.8 | 10.5 | 5.8 | 1.4 |
| 4 (DE, PA) | 15,592 | 59.0 | 43.5 | 88.4 | 0.7 | 6.8 | 3.1 | 1.0 |
| 5 (DC, MD, VA, WV) | 18,879 | 56.8 | 35.3 | 85.7 | 1.1 | 8.1 | 3.9 | 1.2 |
| 6 (GA ,NC, SC) | 25,877 | 56.6 | 27.9 | 85.5 | 1.0 | 8.2 | 4.5 | 0.8 |
| 7 (FL) | 16,725 | 59.6 | 35.4 | 86.3 | 2.6 | 6.0 | 4.0 | 1.1 |
| 8 (AL, MS, TN) | 16,918 | 56.1 | 32.5 | 87.7 | 0.7 | 7.4 | 3.4 | 0.8 |
| 9 (IN, KY, OH) | 22,446 | 56.4 | 44.9 | 80.1 | 0.6 | 13.7 | 4.5 | 1.1 |
| 10 (IL) | 14,123 | 56.5 | 43.5 | 85.0 | 1.4 | 8.8 | 3.9 | 0.9 |
| 11 (MI, MN, ND, SD, WI) | 22,505 | 55.7 | 51.8 | 82.3 | 0.6 | 12.9 | 3.3 | 0.8 |
| 12 (IA, KS, MO, NE) | 12,631 | 57.0 | 46.6 | 78.2 | 1.2 | 14.5 | 5.1 | 0.9 |
| 13 (AR, LA, OK) | 12,743 | 56.2 | 33.1 | 87.4 | 0.4 | 8.2 | 3.6 | 0.4 |
| 14 (TX) | 22,621 | 56.2 | 32.7 | 89.1 | 0.5 | 5.9 | 3.9 | 0.5 |
| 15 (AZ, CO, NM, NV, UT, WY) | 12,557 | 55.8 | 42.2 | 84.2 | 1.0 | 8.8 | 5.1 | 1.0 |
| 16 (AK, ID, MT, OR, WA) | 8,982 | 54.2 | 50.3 | 79.0 | 3.3 | 12.5 | 3.8 | 1.4 |
| 17, 18 (CA, HI) | 33,942 | 56.9 | 38.7 | 86.7 | 0.1 | 8.5 | 4.0 | 0.7 |
| Unknown Network | 4,039 | 45.0 | 85.4 | 87.9 | 0.9 | 5.5 | 2.1 | 3.5 |
| TOTAL | 307,967 | 55.7 | 39.1 | 84.9 | 0.9 | 9.1 | 4.1 | 0.9 |

[a] *For December 31, 1997, only; covers 92% of functioning transplants (all ages).*

[b] *Percentages add to ~ 100 across for dialysis only*

*Source: Reference Tables C.7, C.8, and Special Analysis*

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**Table III-1**

for 1995, 1996, and 1997, rather than 1997 data alone. This is done to provide stability for the reported percentages. Compared to the national summary data (labeled TOTAL), this table shows large variations for certain regions. The median age for prevalent patients (alive on December 31 of each year) varied by region from 54.2 to 59.6 for an overall median age of 55.7 years.

The fraction of ESRD patients with a functioning transplant had an almost two-fold range from the highest to the lowest region (27.9 to 51.8 percent) with an average of 39.1 percent. Patients over 65 years comprise a large percentage of the total prevalent ESRD population but only a small percentage of prevalent patients with functioning transplants. Therefore to reduce the extent to which differences in age distributions among the Networks might be contributing to Network variations in the fraction of ESRD patients with a functioning transplant, only patients younger than 65 years were considered in this analysis.

The fraction of dialysis patients on CAPD ranged from 5.9 to 14.5 percent accounting for an overall average of 9.1 percent of all dialysis patients. The relatively high percentages observed in Midwestern and Mountain states may be related, in part, to the distances of patients from their nearest dialysis facility, as previously described in the USRDS 1991

Annual Data Report. CCPD also had a wide range of utilization across different regions (3.0 to 6.2 percent). The utilization of CCPD versus CAPD deserves further study.

The fraction of dialysis patients treated by home hemodialysis shows a large variation by region. Two regions appear to be promoting home hemodialysis (3.3 percent and 2.6 percent utilization fractions), while the remainder range between 0.1 and 1.4 with an overall average of 0.9 percent utilization (Table III-1). No correlation of the utilization of home hemodialysis with that of other forms of home dialysis (CAPD or CCPD) is obvious from this table.

Although it is difficult to fully explain the observed regional differences, it is important to draw attention to them, since the observed variations from the national average may stimulate local or regional efforts to be directed towards improving patient access to all treatment modality options. Future studies need to address causes for these large regional differences in modality utilization.

The steadily growing disparity between the population wait-listed for kidney transplantation and the number of cadaveric transplants performed annually during the years 1988-97 is highlighted in Figure III-4. These data are based on the Annual Facility Survey completed by all Medicare-approved providers at the end of each year (see Reference Tables, Section I). The number of cadaveric transplants performed per year had increased substantially before 1986 but is relatively unchanged since that time. This is in sharp contrast with the steeply increasing number of patients being wait-listed for cadaveric transplants in recent years. By prolonging the waiting period to transplantation, this widening gap between supply and demand for cadaveric kidneys has serious implications for ESRD patient morbidity, mortality, quality of life and for the costs of delivering ESRD care. An urgent need exists both for large increases in cadaveric and living organ donations and for improvements in long-term allograft survival.

The number of living donor transplants has increased slightly, though steadily, since 1989. Living donor transplantation provides superior patient and graft survival (Chapter VII). Figure III-5 shows in more detail the total number of transplants by donor type and by year for the period 1989-1997. Both living related and living unrelated modes of transplantation have been increasing, but by far the greatest percent change within the different categories of organ donation has been in the as yet small group of living unrelated donor transplants (Chapter VII, Figure VII-2). More details about the transplant process and the demographics of transplant donors and recipients are given in Chapter VII.

**Patients on Waiting List for Kidney Transplant and Cadaveric Donor Transplants by Year, 1988-97**

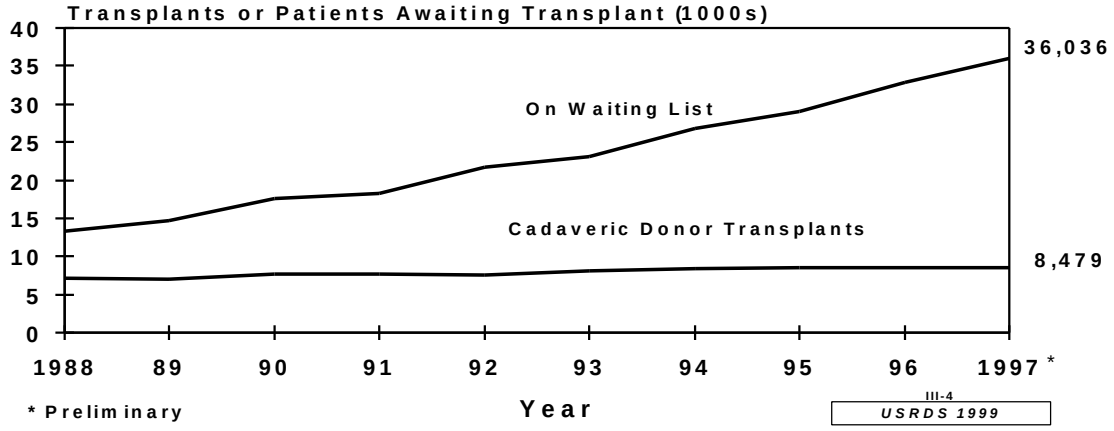


**Figure III-4**

*Counts of patients on cadaveric renal transplant waiting list and counts of renal transplants from a cadaveric donor by year, 1989-1997. Source: Reference Table I.9.*

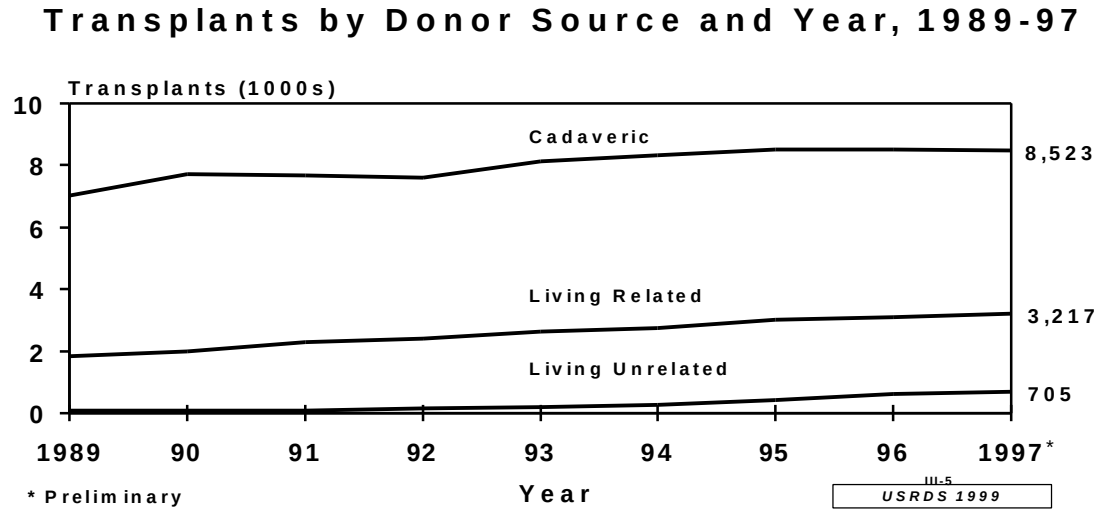


**Figure III-5**

*Counts of renal transplants from cadaveric, living related, and living unrelated donors by year, 1989-1997. Source: Reference Tables I.9 and F.1.*

## Utilization of ESRD Modalities by Patient Characteristics

Numerous factors influence the selection of treatment modality (Nissenson). Consistent with analyses from previous years, wide variations again existed, in 1997, in the patterns of utilization by patient characteristics of the various treatment modalities. These are evident from Table III-2 which describes the proportionate utilization of each modality of renal replacement therapy (including treatment by a functioning transplant) by age, sex, race, and cause of ESRD groups, as a percentage of all ESRD treatment.

By age group, younger patients had a much higher fraction of functioning transplants than older patients did. Over two thirds (68.1 percent) of ESRD patients in the under-20 age-group had a functioning transplant, while 48.8 percent in the 20–44 age group; 31.6 percent in the 45-64 age group; and only 6.8 percent in the 65-year and older age group had functioning renal transplants. The percentage using CAPD/CCPD ranged from 7.8 to 13.2 percent, being highest in the youngest age group. Center hemodialysis was used infrequently in the pediatric ages, accounting for only 17.3 percent of patients under age 20. In contrast, the oldest age group (>65 years) was primarily (84.2 percent) treated by center hemodialysis. Home hemodialysis showed increasing fractions in older age groups.

Males had a higher percentage of functioning transplants (30.8 percent) compared to females (24.8 percent), which agrees with the finding of greater transplantation rates for males in multivariate analyses (Gaylin; Webb; Bloembergen; Wolfe).

Table III-2 also shows large differences in the distribution of ESRD treatment modalities by race. In the category of functioning transplant, Blacks were under-represented by a wide margin with only 15.6 percent of Blacks compared to 28 percent of non-Blacks treated by this modality. The differences for the fractions with functioning transplants are likely due to differences by race both in transplantation rates (Gaylin; Wolfe) and in transplant graft survival. Both issues are discussed in more detail in Chapter VII.

Treatment modality use by major cause of ESRD is also shown for prevalent patients in 1997. The fraction of patients with a functioning transplant was much higher for patients with glomerulonephritis and cystic kidney disease (44.6 percent and 50.6 percent respectively). In contrast, for prevalent patients with diabetes or hypertension as a cause of ESRD only 17.9 and 16.3 percent had a functioning transplant, respectively. Some of the differences in modality utilization among these primary disease categories may be explained by confounding effects of age

## ESRD Treatment Modality by Age, Sex, Race, and Primary Disease, 1997

| Patient Characteristic | N | ESRD Modality (%)[a] Functioning Transplant | Center Hemo | Home Hemo | CAPD | CCPD | Other PD | Unknown |
|---|---|---|---|---|---|---|---|---|
| **All Patients** | **307,967** | **28.0** | **62.3** | **0.6** | **5.4** | **3.1** | **0.1** | **0.4** |
| Age 0-19 | 5,539 | 68.1 | 17.3 | 0.4 | 2.9 | 10.3 | 0.4 | 0.6 |
| Age 20-44 | 76,882 | 48.8 | 41.5 | 0.4 | 5.7 | 3.2 | 0.1 | 0.3 |
| Age 45-64 | 119,779 | 31.6 | 58.4 | 0.6 | 6.0 | 3.1 | 0.1 | 0.3 |
| Age 65+ | 105,767 | 6.8 | 84.2 | 0.7 | 4.8 | 2.8 | 0.1 | 0.6 |
| Male | 167,478 | 30.8 | 60.1 | 0.6 | 5.0 | 3.1 | 0.1 | 0.4 |
| Female | 140,489 | 24.8 | 65.0 | 0.5 | 6.0 | 3.2 | 0.1 | 0.4 |
| Native American | 4,620 | 20.7 | 69.0 | 1.3 | 6.1 | 2.4 | 0.0 | 0.2 |
| Asian/Pacific Islander | 11,076 | 28.8 | 60.5 | 0.4 | 6.3 | 3.6 | 0.2 | 0.2 |
| Black | 97,906 | 15.6 | 76.8 | 0.5 | 4.3 | 2.5 | 0.1 | 0.3 |
| White | 188,732 | 34.7 | 54.7 | 0.6 | 5.9 | 3.5 | 0.1 | 0.5 |
| Other/Unknown | 5,633 | 26.2 | 62.7 | 0.2 | 6.2 | 3.7 | 0.3 | 0.5 |
| Diabetes | 102,426 | 17.9 | 72.2 | 0.5 | 5.8 | 3.2 | 0.1 | 0.4 |
| Hypertension | 73,644 | 16.3 | 74.9 | 0.5 | 5.0 | 2.8 | 0.1 | 0.4 |
| Glomerulonephritis | 53,094 | 44.6 | 44.8 | 0.6 | 6.1 | 3.5 | 0.1 | 0.4 |
| Cystic Kidney Disease | 14,142 | 50.6 | 39.8 | 0.7 | 5.6 | 3.1 | 0.1 | 0.2 |
| All Other[b] | 64,661 | 39.0 | 51.6 | 0.6 | 4.9 | 3.2 | 0.1 | 0.6 |

[a] *Percentages add across to ~ 100; Preliminary results.*

[b] *Includes other known, uncertain, and missing causes.*

*Source: Reference Tables C.5 and C.6. Includes U.S., Puerto Rico, and territories.*

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**Table III-2**

and/or race. The use of CAPD/CCPD appears to be similar by primary disease group in this table. The effects of demographic variables on access to transplantation have been studied (Gaylin; Bloembergen 1997; Webb; Wolfe). These and other factors are discussed in more detail in Chapter VII.

## Utilization of Dialytic Modalities by Patient Characteristics

The data in Table III-2 can also be used to describe the wide variations in the proportionate utilization, by patient characteristics, of any given dialytic modality as a percent of all dialysis treated patients. This is done by excluding the category of "treatment with a functioning transplant" as a form of renal replacement therapy, and was the approach used to generate Figures III-6 and III-7.

For example, to determine the total utilization of CAPD/CCPD as a percentage of all dialysis therapy the following calculation is made: (100 multiplied by the percent of all ESRD patients treated by CAPD and CCPD combined / 100- percent of all ESRD patients treated with a functioning graft). Thus, CAPD/CCPD accounted for the treatment of 11.8 percent of all dialysis treated patients ( 100*8.5 / (100-28) ). If both other PD and unknown modality was counted as PD, then all PD made up 12.5 percent of all dialysis treated patients. Likewise home hemodialysis was used by 0.6 percent of all ESRD patients but by 0.8 percent of all dialysis patients. For any specific race, sex or age group in Table III-2,

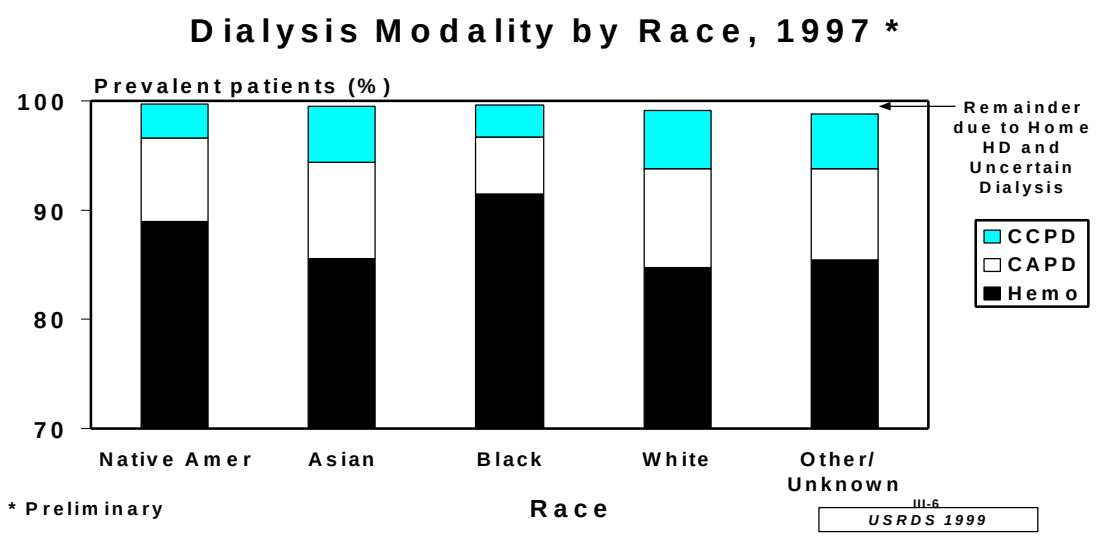


**Figure III-6**

*Dialysis modality use by race among prevalent dialysis patients, 1997. (Note: home hemodialysis is approximately 1 percent.) Source: Reference Table C.5.*

the dialysis modality as a percent of all dialysis patients can be obtained by a similar conversion.

Figure III-6 shows the variation in the distribution of HD, CAPD and CCPD use by five different race groups as a percentage of all prevalent dialysis patients at year-end in 1997. For all groups, HD predominates and accounts for over 80 percent of dialysis patients. The patterns for Whites and Asians are quite similar with relatively large fractions of CAPD and CCPD utilization.

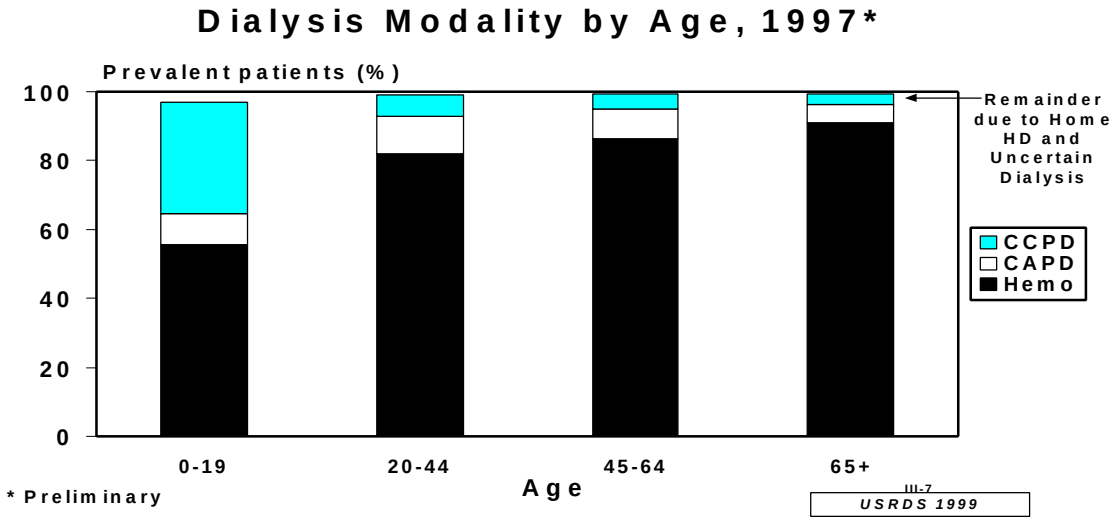


**Figure III-7**

*Dialysis modality use by age, 1997. This figure excludes transplants. (Note: home hemodialysis is approximately 1 percent.) Source: Reference Table C.6.*

These two forms of PD are utilized to a much smaller extent among Black dialysis patients, while Native Americans show an intermediary pattern of PD utilization.

Patient age is an additional factor influencing the use of dialytic modalities. Figure III-7 shows a pattern of modality utilization for pediatric dialysis patients that is very different from adult patients. In children, PD is used in almost half of the dialysis patients and mostly as CCPD. More detail is provided by subgroups of pediatric ages in the chapter on pediatric ESRD (Chapter VIII). For adult patients, older age is associated with decreasing use of CAPD and of CCPD and increasing utilization of HD.

Many factors influence the choices of dialytic modality including distance to a center, functional independence, personal preference, provider preference, education, socio-economic parameters, and comorbid conditions (USRDS 1992). Factors such as these may explain some of the variation discussed above. Future trends may be influenced by additional variables such as increasing utilization of CCPD, and/or greater attention to dosing of PD.

## Dose of Dialysis

The dose of dialysis can be described as the dialysis Kt/V which is the dialyzer clearance of urea times duration of dialysis divided by urea distribution volume. Sargent and Gotch (1985) described Kt/V as calculated from pre- and post-dialysis BUN and the next pre dialysis BUN through urea kinetic modeling. This approach has been simplified by Daugirdas to a formula which uses only pre and post dialysis BUNs and weights plus duration of dialysis to calculate single pool or double pool Kt/V (Daugirdas, 1995). An alternative method is to use the urea reduction ratio (URR), which is the change in BUN (pre-minus post-dialysis) divided by the pre-dialysis BUN. USRDS studies used the Daugirdas formula to estimate single pool Kt/V. It demonstrated that Kt/V and URR had a very high correlation with each other and both measures showed an inverse correlation with mortality risk (Held, 1996). These measures however

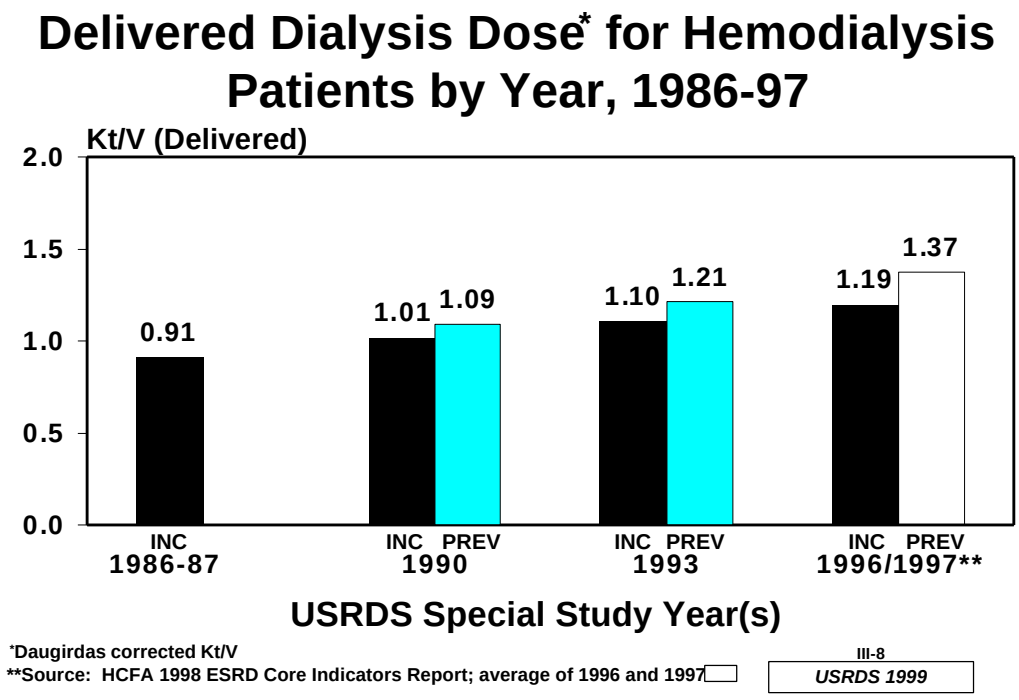


**Figure III-8**

*Delivered dose of dialysis for hemodialysis patients, by year, 1986-1997. Source: Special Analysis; HCFA 1998 ESRD Core Indicators Report.*

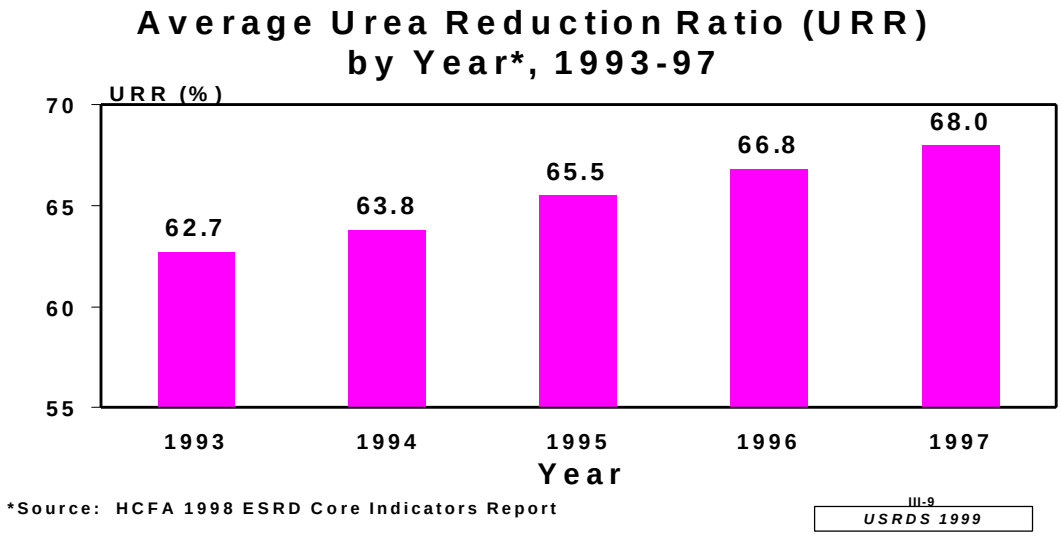


**Figure III-9**

*Average urea reduction ratio by year, 1993-1997. Source: HCFA 1998 ESRD Core Indicators Report.*

are limited in that they indicate the dialysis dose only for small molecules. A recent study suggests that both Kt/V for urea and Kt/V for vitamin B12 as a marker of middle molecules are independently and significantly associated with mortality risk (Leypoldt). This means that, at the same Kt/V for urea, a higher clearance of middle molecules is associated with lower mortality risk and that, at the same Kt/V for middle molecules, a higher Kt/V for urea is also independently associated with lower mortality risk.

The USRDS Special Studies, described in detail in Chapter I, provide data to describe trends in dialysis dose prescriptions in large national random samples of dialysis patients over the decade from 1986 to 1996. Figure III-8 summarizes these data graphically and illustrates trends in delivered hemodialysis dose according to ultrafiltration and urea reduction (single-pool) corrected Kt/V (Daugirdas).

Incident hemodialysis patients in these samples were those whose dialysis dose was reported on average at 1 to 2 months into renal replacement therapy. In 1990 and 1993 the prevalent patient samples were of individuals greater than 1 year on dialysis at the time dialysis dose was reported. Thus, the average prevalent patient in these samples was likely to have minimal residual renal function. The 1996 and 1997 prevalence sample is from the 1998 ESRD Core Indicators Report and includes some patients less than 1 year on dialysis. The consistent finding to be emphasized from all these studies is that the delivered dialysis dose has consistently increased over time for both incident and prevalent patients. The increase was 1.01 to 1.19 for incident patients and 1.09 to 1.37 for prevalent patients from 1990 to 1996. A reasonable speculation as to the reason for the consistently higher delivered dialysis dose in the prevalent versus incident patient samples, at each timepoint, was the enrichment of the incident patient groups with individuals, who by virtue of having more residual renal function, received on average less dialysis. Figure III-9 summarizes time trends in the average urea reduction ratios (URR) for prevalent patients on hemodialysis with data from the 1998 ESRD Core Indicators Report. Again, this confirms a steadily increasing dose prescription over the 5 years from 1993 to 1997 from a URR of 62.7 percent in 1993 to 68.0 percent in 1997.

Figure III-10 reflects the increased attention in the renal community to individualizing peritoneal dialysis prescriptions in order to achieve more uniform and better clearances, both preceeding and following the publication of the results of the CANUSA study in 1996. Both the average weekly Kt/V for urea, and the average weekly creatinine clearance, have increased steadily by year in PD patients from 1995 to 1998 (data shown for CAPD patients; similar increases noted for CCPD patients

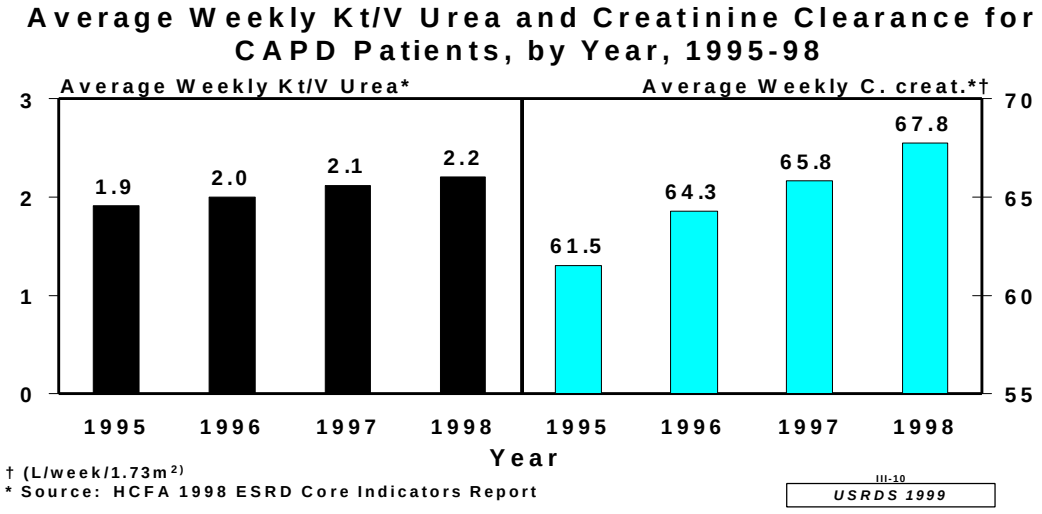


**Figure III-10**

*Average weekly Kt/V urea and average weekly creatinine clearance for CAPD patients, by year, 1995-1998. Source: HCFA 1998 ESRD Core Indicators Report.*

but data not shown). Average weekly Kt/V for Urea increased from 1.9 to 2.2 while average Creatinine Clearance increased from 61.5 to 67.8.

## Membrane Type in Hemodialysis

The type of dialyzers used in the United States have gradually changed over time, from

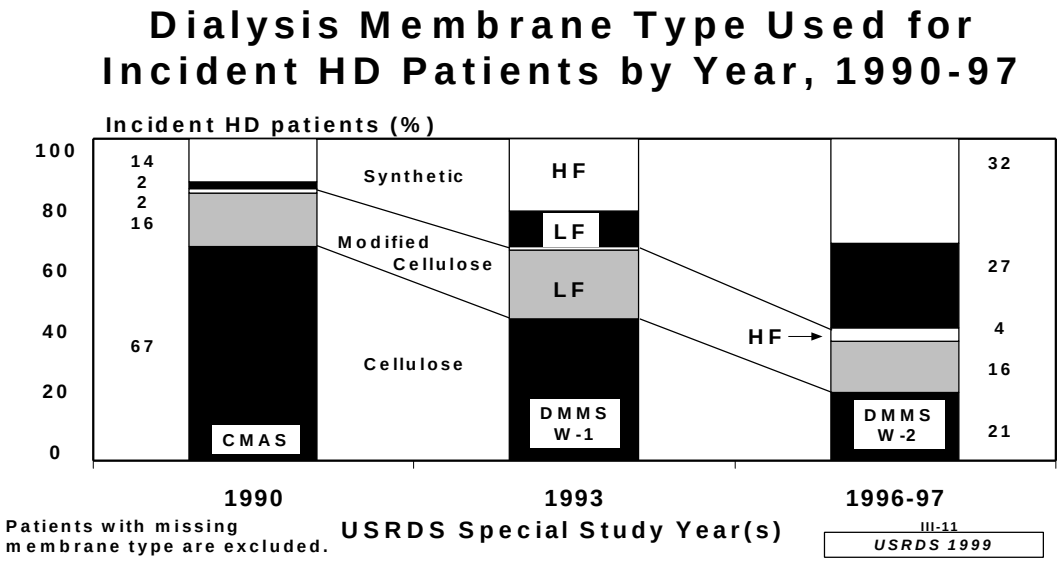


**Figure III-11**

*Dialysis membrane type use among incident hemodialysis patients, by year 1990, 1993, and 1996-1997. Source: Special Analysis.*

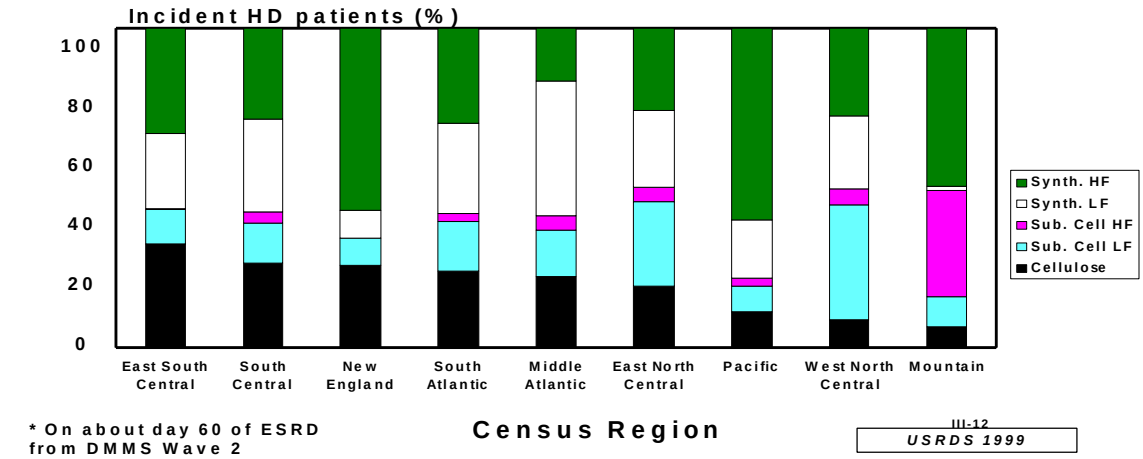


**Figure III-12**

*Dialyzer membrane type (cellulose, modified cellulose low flux, modified cellulose high flux, synthetic low flux, or synthetic high flux) use among incident hemodialysis patients from DMMS Wave 2 by Census region, 1996-97. Source: Special Analysis.*

predominantly unmodified cellulosic membranes to predominantly synthetic membranes. The USRDS Special Studies have been instrumental in gathering information about the membrane type used in hemodialysis. A new analysis of utilization patterns for five categories of dialysis membrane is presented here. The membrane types are as follows: synthetic high-flux, synthetic low-flux, high-flux substituted cellulose, low-flux substituted cellulose, and unmodified cellulosic membranes.

Figure III-11 shows data on membrane utilization from national random samples of incident hemodialysis patients from 1990 to 1996-97. Over this period, the utilization of synthetic high-flux membranes increased dramatically. Synthetic, high-flux membranes accounted for only 14 percent of all dialyzers in 1990, but utilization increased such that these membranes accounted for almost one third of all dialyzers in use in 1996-97.

Utilization of synthetic, low-flux dialyzers also increased dramatically from 2 percent to 27 percent of all dialyzers over the same period. Both types of synthetic membranes are primarily based on polysulfone. The fractional utilization of substituted cellulosic membranes (mostly cellulose acetate) changed little, but utilization of unmodified cellulosic membranes declined steeply from 67 percent in 1990 to 21 percent in 1996-97.

Figures III-12 shows the type of dialysis membrane in use by census region, in incident HD patients, in 1996-97. Data were recorded on about day 60 of ESRD treatment in DMMS Wave 2. Wide variations by region were seen in the use of all membrane types. Synthetic high-flux membranes for instance varied by geographic region from 15 to 60 percent. With the exception of one region the least utilized membrane category was that of substituted cellulosic, high-flux membranes.

Future studies should explore reasons for these large variations in membrane use and further evaluate the possible correlation between type of membrane use and mortality (Hakim 1996). In addition, given the changes in both HD and PD dosage practices (and the changes in membrane utilization in HD), it again becomes imperative to compare the effects of these two choices in hemodialysis perscription on patient outcomes in an analysis that is carefully controlled for other confounding variables. The USRDS plans to pursue such an analysis in the future, based on outcomes data that is currently being accrued prospectively on a cohort of over 4,000 incident hemodialysis and peritoneal dialysis patients in Wave 2 of the USRDS Dialysis Morbidity and Mortality Study (DMMS).

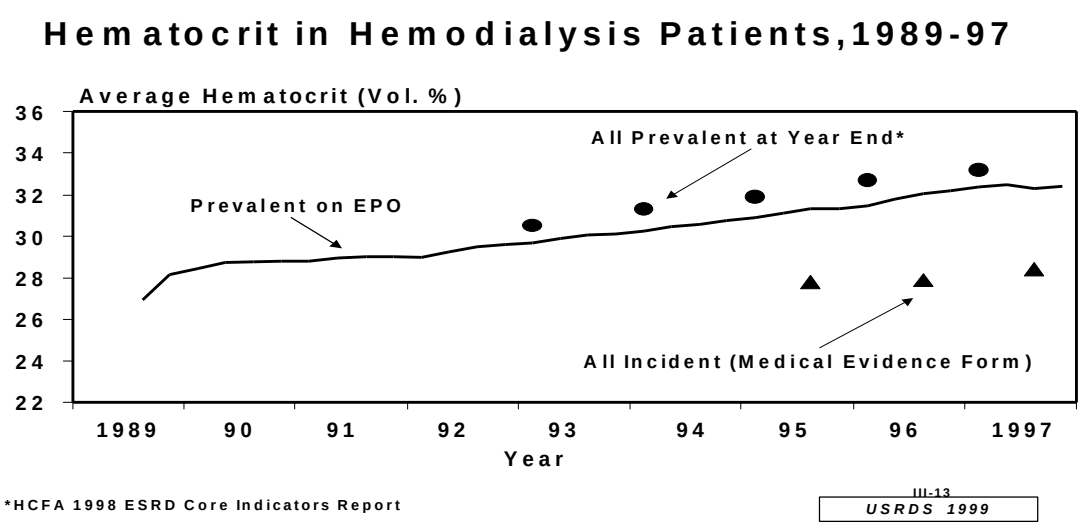


**Figure III-13**

*Average hematocrit for hemodialysis patients, 1989-1997. Source: Special Analysis; HCFA 1998 ESRD Core Indicators Report.*

## Hematocrit in Hemodialysis Patients

The 1997 USRDS Annual Data Report reported the mean hematocrit for EPO treated Medicare hemodialysis patients and demonstrated a steady increase from 1989 to 1995. Currently, multiple data sources are available to evaluate trends in average hematocrit over time. Figure III-13 shows; (1) the findings of the HCFA 1998 Core Indicators Project, (2) an analysis of Medicare payment records among patients treated with EPO, and (3) an analysis of incident patients with a Medical Evidence Form for 1995-97. The 1998 ESRD Core Indicators Project (HCFA) reported the distribution of hematocrit values for a random sample of adult (aged $\geq$ 18 years), in-center hemodialysis patients, by year for 1993-1997 and showed that average hematocrit for the five-year period increased from 30.5 percent to 33.2 percent.

A corresponding increase from 30.1 percent in the last quarter of 1993, to 32.4 percent in the last quarter of 1997, is reported by the USRDS for rhEPO-treated patients. This is consistent with a prior USRDS finding, which showed that patients receiving EPO have a lower hematocrit than those not requiring EPO (USRDS 1997). A comparable increase is demonstrated by analysis of data from the Medical Evidence Form. Over a three-year period, 1995-1997, the hematocrit increased from 27.8 percent to 28.4 percent. The fact that values are lower at the start of ESRD may be explained by the dilutional effect of fluid overload before the first ESRD treatment and/or a lack of EPO treatment prior to the start of dialysis (see Chapter IV). Overall, Figure III-13 demonstrates, from three different patient populations and three sources, a consistent trend toward improved management of anemia in hemodialysis patients.

## Summary

While the number of patients being treated by both hemodialysis and by functioning transplants continued to increase, 1996 and 1997 data show a leveling off and a small decrease in the total number of patients being treated by peritoneal dialysis. Among PD patients, the utilization of CCPD is expanding. The number of patients wait-listed for transplantation continues to grow disproportionately to the number of transplants being performed annually. The decade from 1986-1996 has seen substantial increases in hemodialysis dose in both incident and prevalent patients. Delivered peritoneal dialysis doses also progressively increased over the years 1995 to 1998. Average hematocrit levels rose in HD patients, but remain significantly lower in incident versus prevalent patients. An additional trend, which emerged from 1990 to 1997, was the

increasing utilization of synthetic dialyzers (both high-flux and low-flux) in preference to the more traditional unmodified cellulosic dialyzers.

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