Chapter III

Treatment Modalities for ESRD Patients

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

Several modalities are available for the treatment of end-stage renal disease (ESRD), including as main categories renal transplantation, hemodialysis, and peritoneal dialysis. In this chapter hemodialysis (HD) is subdivided into center HD, which is the most common modality, and home HD. Peritoneal dialysis (PD) refers predominantly to continuous ambulatory PD (CAPD) and continuous cycling PD (CCPD) with a small subgroup of other forms of PD. Renal transplantation may be from a living donor (usually related) or a cadaveric donor and is discussed in more detail in Chapter VII.

During the course of renal replacement therapy patients may move from one treatment modality to another, for example from CAPD to transplantation and, after transplant failure, to hemodialysis and perhaps a second transplant. The following sections review the different treatment options briefly, discuss the use of different modalities and trends over time, and examine demographic differences in patterns of modality utilization. The recent Wave 2 of the USRDS Dialysis Morbidity and Mortality Study allows description of patients and their treatment in more detail for a random sample of patients who started CAPD and HD therapy during 1996. Chapter IV provides early detailed information from this sample.

Treatment Modality Options

For patients reaching ESRD before 1960, no treatment other than dietary modification was available. During the 1960s hemodialysis, peritoneal dialysis and renal transplantation became a reality for ESRD patients (Peters). Before that time dialytic modalities as temporary treatment were saving some patients with acute renal failure and transplants were successful only from identical twins. In 1960 Belding Scribner treated the first patients for *chronic* renal failure. This became possible through the creation of a new vascular access, the external arterio-venous Scribner shunt. The biggest obstacle to chronic use of peritoneal dialysis was overcome by the development during the 1960s of the soft Tenckhoff catheter with Dacron cuffs. These cuffs served to create a bacterial barrier in the subcutaneous tunnel. Renal transplantation from non-identical twins became a reality during the 1960s through improved understanding of immunology and immuno-suppressive 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.

Over 250,000 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). Opinions differ about the quality of life for ESRD patients, but subjectively patients report general satisfaction (Evans, 1985).

Renal transplantation: Renal transplantation from living related and cadaveric donors became a clinical reality during the 1960s (Hamilton). Surgical technique had already been well developed before this time but advances in the understanding and pharmacologic manipulation of the immune response made transplantation from non-identical donors a reality. Tissue typing came into routine use during the 1960s as did the direct 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, Wagner). Despite these developments, cadaveric transplantation has shown only a minor growth in the United States since 1986 due to limited availability of donor organs (Prottas; Chapter VII).

Living donors are predominantly blood relatives, although there has been an increase in recent years in living genetically unrelated transplants. A cadaver donor is a person who is brain dead, such as an accident victim, but who is maintained on artificial life support. Transplantation from a cadaver donor usually requires a prolonged waiting time, averaging close to 2 years, whereas transplantation from a living donor can be scheduled in advance and is more likely to be done as an initial ("preemptive") or early renal replacement therapy. Survival of the transplanted kidney (graft or allograft) is influenced by a variety of factors (Opelz; Held 1994a; Braun) such as HLA matching, duration of organ preservation (warm and cold ischemia time) following removal of the organ, presence or absence of panel reactive antibodies, patient demographic factors, rejection episodes, immunosuppressive drug regimens, etc. These factors are described further in Chapter VII.

Hemodialysis: The artificial kidney (dialysis) removes toxins and excess fluid via extracorporeal circulation of blood through the dialyzer. 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 dialyzers are commonly reprocessed for multiple use by the same patient.

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 a short daytime or slow nighttime dialysis (Pierratos).

Peritoneal dialysis: Using the peritoneal membrane, this alternative dialytic therapy requires placement of a catheter into the abdominal cavity and repeated instillations and drainage of sterile dialysate. Because of concentration gradients, toxins move from the plasma to the dialysate during the dwell time, which usually lasts for several hours in CAPD (shorter in other forms of 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 exchanges of 2-3 liters dialysate on a daily basis at home. Continuous cycling PD (CCPD) is also predominantly a home treatment and 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 22 percent in 1996 (see Chapter IV). Combinations of CAPD and CCPD have recently been utilized, particularly in large patients with no residual renal function (Diaz-Buxo). Intermittent PD (IPD) with exchanges of dialysate three to seven times weekly for 8 to 12 hours is performed with the cycle (also an automated PD). However, with IPD the abdomen is empty when disconnected from the cycler (see Chapter IV). 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

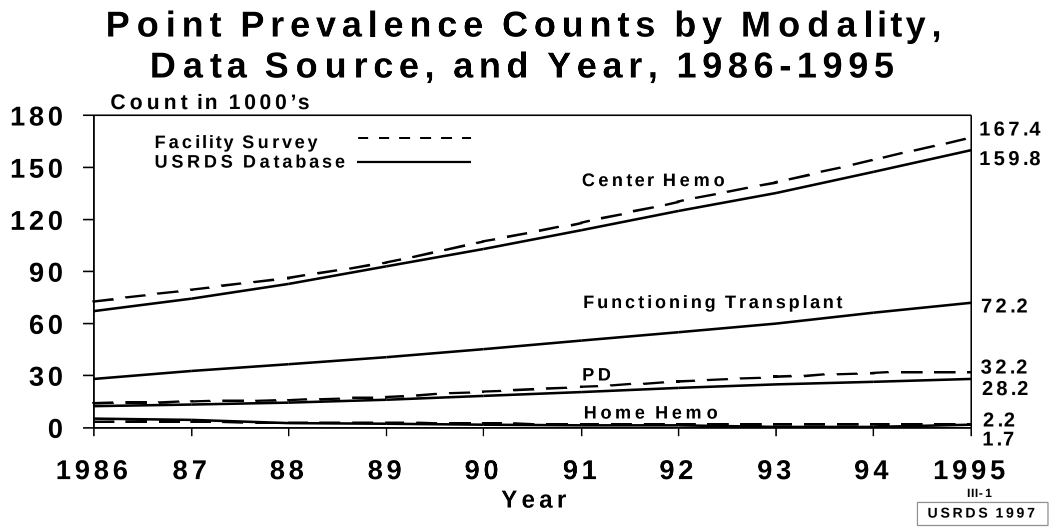

Figure III - 1

Point prevalence counts of ESRD patients by treatment modality, data source, and year, 1986-1995. Percentages include Puerto Rico and U.S. Territories. Source: C.1, I.12

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. Co-morbid 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 a low delivered dose of CAPD could prompt some switching to hemodialysis once residual renal function is lost.

Data for Modality Analyses

The USRDS uses a complex analytical process, examining a variety of data sources, to determine longitudinally the treatment modalities for individual patients in the database. Additionally, the facility surveys of the ESRD Networks and HCFA billing data are used. The actual process is described in greater detail in Chapter XII. 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 Medicare ESRD patients on December 31 is obtained from two sources: 1) the USRDS longitudinal patient treatment files ("database") for all ESRD patients and 2) the year-end Facility Survey of all Medicare-approved dialysis units. Figure III-1 shows these counts for 10 years, 1986-95. Data for the most recent year may represent a low estimate because of somewhat incomplete data. While both report the year-end point prevalence, the Facility Survey counts are slightly higher because they include both Medicare and non-Medicare patients. The magnitude of the undercount in the USRDS database is estimated to be in the 6 to 7 percent range which corresponds with the observation that about 93 percent of all ESRD patients are insured by Medicare and can therefore be expected to be counted by the USRDS.

The overall number of patients treated has increased steadily as shown by the count of patients on each treatment modality. The only exception is the small home hemodialysis group, which showed little change 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 with over 72,000 patients. Transplant recipients who lost their transplant function and returned to dialysis are shown

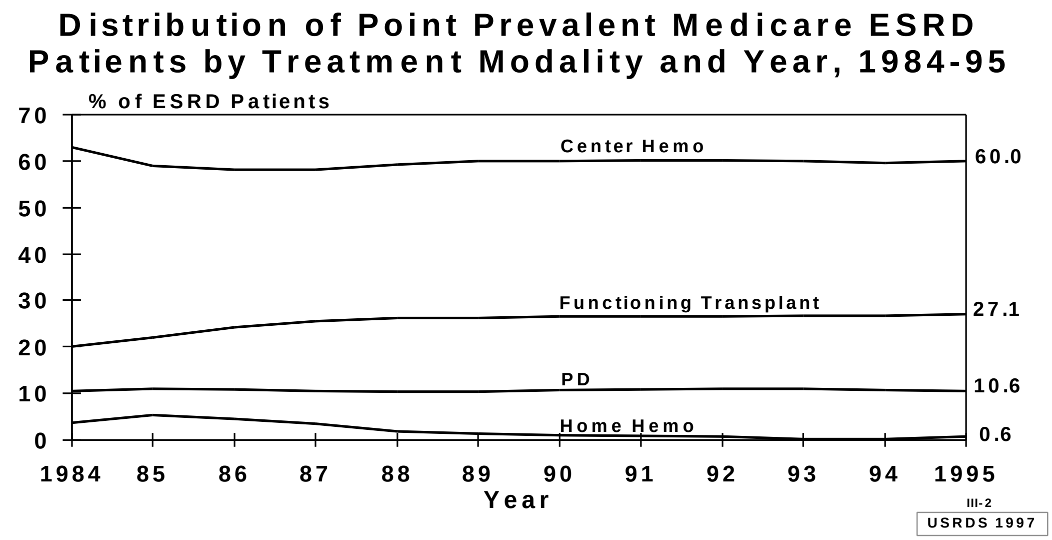

Figure III - 2

Percent distribution of prevalent ESRD patients by treatment modality and year, 1984-1995. Percentages include Puerto Rico and U.S. Territories. Source C.1

in the appropriate dialysis group in the year-end point prevalence counts.

Peritoneal dialysis, mostly CAPD and CCPD, has been the third most common form of ESRD therapy. During the early 1980s, the use of CAPD showed a relatively steep increase (see earlier USRDS reports). Since 1988, however, the percent change per year for each of the three major groups showed nearly the same rate of increase.

Figure III-2 shows the same data as a percent distribution of patients by modality for each year from the USRDS database. This figure 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 VII). However, the relatively constant percentage since

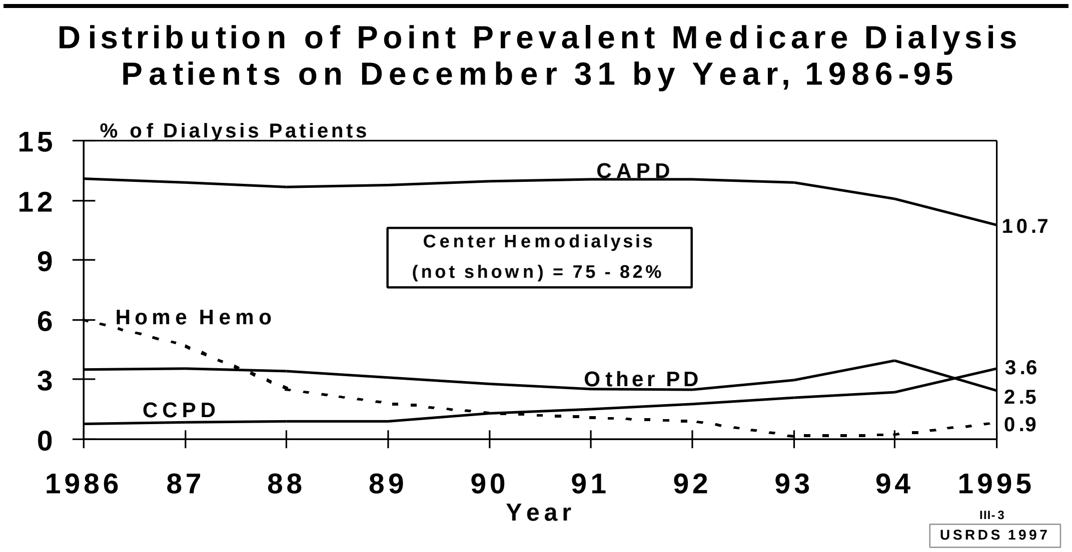

Figure III - 3

Percent distribution of prevalent dialysis patients, by treatment modality and year, 1986-1995. Center hemodialysis not shown. Percentages include Puerto Rico and U.S. Territories. Source C.1

1988 is likely a reflection of the scarcity of available organ donors. The fraction of patients treated with peritoneal dialysis has been fairly constant since the mid 1980s. At the end of 1995, peritoneal dialysis patients accounted for 10.6 percent of all ESRD patients and approximately 18 percent of all dialysis patients. Before the mid 1980s, center hemodialysis had decreased relative to other modalities (Figure III-2 and earlier USRDS reports), yet its total numbers showed a steady annual increase (Figure III-1). Since 1988, the percent distribution for all modalities has been remarkably stable, suggesting similar fractional growth for each modality. Only the small group of patients utilizing home hemodialysis has remained low, perhaps with a first sign of an increase in 1995.

There were 1 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, 1995, are automatically placed in this category according to definitions outlined in Chapter XIII. Despite this, essentially all prevalent Medicare patients are accounted for in this analysis.

The distribution of patients on home hemodialysis and forms of peritoneal dialysis is shown in Figure III-3. When adding center hemodialysis (not shown) to the percentages in this figure, the numbers would add to 100 percent of all dialysis patients (note that figure III-2 indicates percentages of all ESRD patients, which includes patients with functioning transplants). The use of CCPD increased during the 1980s and early 1990s, an increase that was particularly steep in 1995. As of December 1995, CCPD accounted for approximately 3.6 percent of all dialysis and 24.5 percent (2.6/10.6) of the peritoneal dialysis patients. These fractions reflect a clear increase for CCPD in recent years. Intermittent peritoneal dialysis has been declining and is rarely used. Patients treated with other PD accounted for only 2.5 percent of all dialysis patients, and patients with unknown or uncertain dialysis accounted for 2 percent of all dialysis patients at the end of 1995. The fraction treated by CAPD has shown a decrease since 1993.

Regional differences in the utilization of various

Living Medicare Patients on December 31
By Treatment Modality, By Network
1993 Through 1995

Network Number (State)	Total Count[a]	Functioning Transplant (%) Age 0-64 only[a]	Median Age[a]	Dialysis Modality (%)[b] Center Hemo	Home Hemo	CAPD	CCPD	Other PD/ Unknown
1 (CT,MA,ME,NH,RI,VT)	11,239	47.0	58.4	78.5	0.4	13.2	4.1	3.8
2 (NY)	18,447	32.7	57.3	81.6	0.4	13.3	1.9	2.9
3 (NJ, Puerto Rico, Virgin Isl.)	11,485	28.8	57.0	78.8	0.3	13.5	3.8	3.6
4 (DE, PA)	13,687	40.4	59.0	84.7	0.3	9.7	1.9	3.3
5 (DC, MD, VA, WV)	15,661	35.1	56.4	81.5	0.6	11.4	2.1	4.3
6 (GA ,NC, SC)	22,012	27.5	56.2	82.9	0.4	11.0	3.5	2.2
7 (FL)	14,106	35.9	59.7	85.0	0.3	8.3	2.7	3.7
8 (AL, MS, TN)	14,368	32.3	55.8	86.2	0.6	9.1	2.0	2.1
9 (IN, KY, OH)	19,316	44.6	56.5	75.2	0.3	17.0	2.7	4.9
10 (IL)	12,285	42.7	56.6	82.4	0.6	11.1	2.9	2.9
11 (MI, MN, ND, SD, WI)	19,149	51.1	55.6	78.5	0.4	16.5	1.8	2.8
12 (IA, KS, MO, NE)	10,978	47.5	56.9	75.3	0.8	17.9	3.6	2.3
13 (AR, LA, OK)	10,941	33.9	56.3	84.1	0.2	11.6	2.3	1.7
14 (TX)	19,045	33.1	55.6	87.0	0.3	7.7	2.9	2.1
15 (AZ, CO, NM, NV, UT, WY)	10,584	41.6	55.0	80.7	0.4	11.5	3.9	3.4
16 (AK, ID, MT, OR, WA)	8,249	46.4	53.3	76.3	2.5	15.2	2.6	3.4
17, 18 (CA, HI)	28,921	38.9	56.8	83.8	0.1	10.1	2.8	3.2
Unknown Network	5,753	23.4	-	86.5	0.5	6.2	1.5	5.2
TOTAL	266,226	37.9	56.6	81.9	0.4	11.8	2.7	3.1

[a] *for December 31, 1995, only*
[b] *Percentages add to ~ 100 across for dialysis only*
Source: Reference Tables C.7, C.8, special analysis

Table III - 1

treatment modalities are described as the percent distribution of patients by modality in each of the 18 ESRD Networks in Table III-1. Percentages in the dialysis modality columns are calculated from point prevalences in 1993, 1994, and 1995, rather than 1995 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 in 1995 (alive on December 31) varied by region from 53.3 to 59.7 for an overall median age of 56.6 years. For the assessment of the percent of patients with a functioning transplant, only patients aged under 65 years were considered. The fraction of ESRD patients with a functioning transplant had an almost two-fold range from the highest to the lowest region (27.5 to 51.1 percent) with an average of 37.9 percent.

The fraction on CAPD ranged from 7.7 to 17.9 with an average of 11.8 percent of all dialysis patients. The relatively high percentages observed in Midwestern 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 was used in 2.7 percent of dialysis patients and also had a wide range of utilization (1.8 to 4.1 percent). The utilization of CCPD versus CAPD deserves further study.

The fraction of patients treated by home hemodialysis shows a large variation by region. One region appears to be promoting home hemodialysis (2.5 percent), while the remainder range between 0.1 and 0.8 with an average of 0.4 (Table III-1). No correlation of the utilization of home hemodialysis with that of other forms of home dialysis (CAPD or CCPD) is obvious in 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 activity in renal transplantation by year is shown in Figure III-4 as the numbers of living donor and cadaveric donor renal transplants performed per year for 1986-95. 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 steeply before 1986. Only a small increase can be observed since 1986. The relatively stable number of cadaveric transplants performed in recent years is in sharp contrast with the steeply increasing number of patients on the waiting list for cadaveric transplants. This widening gap between supply and demand for cadaveric kidneys from 1986 through 1995 (Figure III-4) has serious implications, since it

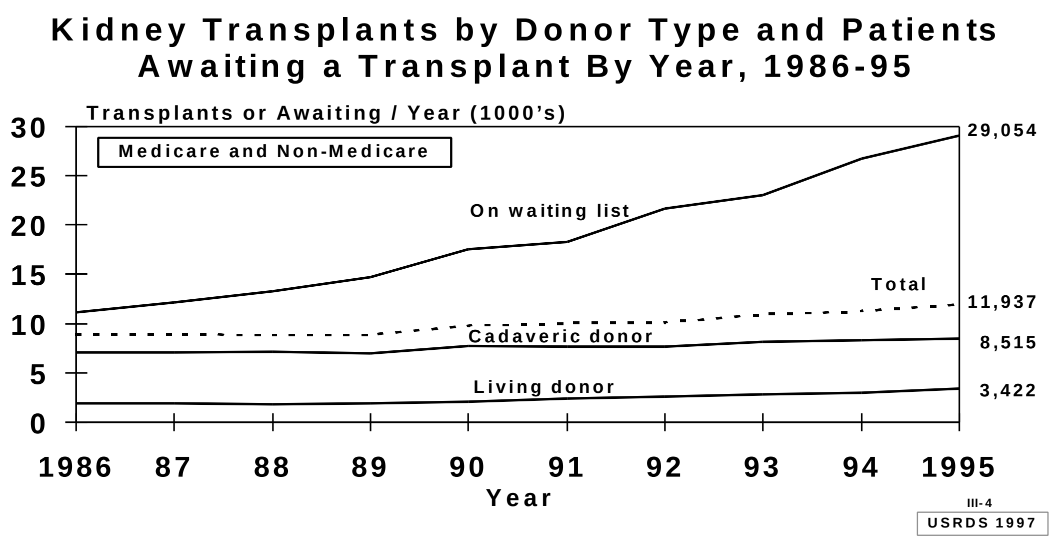

Figure III - 4

Counts of kidney transplants performed among all patients (Medicare and non-Medicare) by donor source and counts of patients on waiting list for cadaveric transplantation, by year, 1986-1995. Source: I.9 prolongs the waiting period for ESRD patients desiring a cadaveric transplant. Thus, this figure clearly demonstrates the need for increased organ donation in the United States.

The number of living donor transplants has increased only slightly, though steadily, since 1989. Living donor transplantation provides superior patient and graft survival (Chapter VII). More details about the transplant process and the demographics of transplant donors and recipients are given in Chapter VII.

Utilization of Modalities by Patient Characteristics

Wide variations in the utilization of the various treatment modalities existed by patient characteristics in 1995. Numerous factors influence the selection of treatment modality (Nissenson) and large differences are observed in international comparisons (Chapter XI). The access to transplantation has been studied (Gaylin; Webb) by demographic and other factors and is discussed further in Chapter VII.

Table III-2 describes modality use by age, sex, race, and cause of ESRD. Overall, center hemodialysis was the most common form of ESRD therapy (60.0 percent) among prevalent patients at the end of 1995. Functioning renal transplant accounted for 27.1 percent, CAPD/CCPD for 10.4 percent and home hemodialysis for 0.6 percent of all ESRD patients treated at the end of 1995. Only 1.8 percent of prevalent patients were treated by other forms of PD or by uncertain or unknown dialysis. When CAPD/CCPD is re-analyzed as the percentage of only dialysis patients (i.e., by excluding the transplant percentages from the denominator), CAPD/CCPD accounted for 14.3 percent of dialysis, whereas all PD made up 16.7 percent of all dialysis when other PD/ unknown modality was counted as PD. There are also large differences in the utilization of CAPD/CCPD among race groups with a much lower percentage of Black patients receiving CAPD and CCPD. Others have found this as well (Golper).

By age group, younger patients had a much higher fraction of functioning transplants than older patients. About two thirds (65.5 percent) of ESRD patients in the under-20 age-group had a functioning transplant, while there were 29.5 percent in the 45-64 age-group and only to 5.8 percent in the 65 year and older group with a functioning transplant. The percentage using

ESRD Treatment Modality for Medicare Patients by Age, Sex, Race, and Primary Disease, 1995

Patient Characteristic	N	ESRD Modality (%)[a] Functioning Transplant	Center Hemo	Home Hemo	CAPD	CCPD	Other PD	Unknown
All Patients	**266,226**	**27.1**	**60.0**	**0.6**	**7.8**	**2.6**	**0.2**	**1.6**
Age 0-19	4,968	65.5	17.7	0.4	3.8	9.2	1.0	2.5
Age 20-44	70,652	48.1	39.2	0.5	7.8	2.7	0.1	1.6
Age 45-64	101,167	29.5	56.8	0.6	8.5	2.5	0.2	1.9
Age 65+	89,439	5.8	82.4	0.7	7.4	2.3	0.1	1.3
Male	143,346	30.2	57.2	0.6	7.4	2.6	0.2	1.7
Female	122,880	23.5	63.3	0.6	8.3	2.6	0.2	1.5
Native American	3,911	21.0	65.5	2.1	8.3	1.6	0.3	1.3
Asian/Pacific Islander	8,760	26.9	59.2	0.7	8.7	2.9	0.3	1.4
Black	84,407	14.9	74.7	0.5	6.4	1.9	0.1	1.5
White	164,520	33.8	52.2	0.7	8.5	3.0	0.2	1.6
Other/Unknown	4,628	18.1	66.4	0.7	7.1	2.5	0.4	4.8
Diabetes	83,143	18.1	68.3	0.5	8.5	2.7	0.2	1.8
Hypertension	65,459	14.9	73.0	0.6	7.6	2.3	0.1	1.5
Glomerulonephritis	48,282	42.7	44.0	0.7	8.3	2.8	0.2	1.3
Cystic Kidney Disease	12,871	46.0	41.1	0.9	7.6	2.8	0.2	1.4
All Other[b]	56,471	37.0	50.8	0.7	6.9	2.6	0.2	1.8

[a] *Percentages add across to ~ 100.*

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

Source: Reference Tables C5,C6

Table III - 2

CAPD/CCPD appeared relatively stable across age groups ranging from 9.6 to 12.9 percent. Center hemodialysis was used infrequently in the pediatric ages, accounting for only 17.7 percent of patients under age 20. In contrast, the oldest age group (>65 years) was primarily (82.4 percent) treated by center hemodialysis. Home hemodialysis showed increasing fractions in older age groups.

Racial differences in modality usage are also apparent in this table. There are large differences in modalities for all other races when compared to Whites. Of note, in the category of functioning transplant, Blacks were under-represented by a wide margin when compared to the average of 27.1 percent. The differences for the fractions with functioning transplants are likely due to differences by race both in transplantation rates (Gaylin) and in transplant graft survival. Both issues are discussed in more detail in Chapter VII.

Home hemodialysis was used by 0.6 percent of all ESRD patients and 0.9 percent of all dialysis patients according to the USRDS/HCFA database. This reflects an increase over the previous 2 years.

Males had a higher percentage of functioning transplants (30.2 percent) compared to females (23.6 percent), which agrees with the finding of greater transplantation rates for males in multivariate analyses (Gaylin; Webb). Males and females utilized CAPD/CCPD at similar percentages (13.7 and 15.0 percent, respectively) when analyzed for all dialysis patients rather than for all ESRD patients.

Table III-2 also shows treatment modality use for prevalent patients by major cause of ESRD. The fraction of patients with a functioning transplant was much higher for patients with glomerulonephritis and cystic kidney disease (42.7 percent and 46.0 percent respectively). In contrast, prevalent patients with diabetes or hypertension as a cause of ESRD had only 18.1 and 14.9 percent with a functioning transplant, respectively. Some of the differences may be related to the age distribution by cause of ESRD and higher transplant rates for younger age groups. The use of CAPD/CCPD appears to be similar by diagnosis group in this table.

Dose of Hemodialysis

Three Special Studies on random samples of United States hemodialysis patients have been performed by the USRDS: The Case Mix Severity Study (CMSS), Case Mix Adequacy Study (CMAS) and the first two waves of the Dialysis Morbidity and Mortality Study (DMMS, Waves 1 and 2). Their respective study start dates were 1986-87, 1990, 1993, and 1996. Each of the first three studies collected information from nearly 6,000 randomly selected dialysis patients, whereas DMMS Wave 2 prospectively collected data on a sample of about 4,000 incident patients. Analyses of these data have been provided in previous USRDS Annual Data Reports, specifically in 1992 for the Case Mix Severity Study and in 1995 for the Case Mix Adequacy Study.

The prescribed hemodialysis dose has been increasing according to comparisons between the 1990/91 CMAS and the 1993/94 DMMS USRDS studies. Similarly, the delivered dialysis dose has increased over time, as was shown in the 1996 ADR, for prevalent patients who had been on ESRD for at least 1 year. Each of the four studies contained a sample of incident hemodialysis patients whose delivered dose was reported at about 1 to 2 months into dialysis therapy. Figure III-5 illustrates the trend of delivered hemodialysis dose according to ultrafiltration and urea reduction (single-pool) corrected Kt/V (Daugirdas). The Case Mix Severity Study recorded for 1986-87 that the delivered dialysis dose was measured in less than 10 percent of patients and averaged 0.91. This increased for incident patients in the 1990 Case Mix Adequacy Study to 1.01 and for corresponding patients in 1993 (DMMS, Wave 1) to 1.10. Preliminary results based on a sample of 958 incident hemodialysis patients from DMMS Wave 2 indicate that the delivered dose in 1996 was even higher, at 1.19.

There has been clear documentation that the dose of dialysis in the United States has been relatively low when compared to European data (Held 1994b) and that a higher dose correlates with a significantly lower mortality risk (Owen; Held 1996).

Prescription for CAPD

Data for the CAPD dose is currently only available for the Case Mix Severity Study since the Case Mix Adequacy Study and the first wave of the DMMS did not include CAPD patients. In that sample approximately two-thirds of CAPD patients had a prescription of four 2-liter exchanges per day. Only 4 percent of patients had larger exchange volumes prescribed, while the prescribed daily dialysate volume was less than 8 liters in 27 percent of patients (USRDS 1992a). Although these data were obtained early in CAPD therapy (at day 30 of

ESRD), they suggest that a low dose of CAPD was prescribed to a large fraction of patients. Nolph and coworkers (1994) have pointed out that a dose of four times 2 liters daily is inadequate for functionally anephric patients weighing more than 65 kg. This weight is near the average of patients starting ESRD therapy. No national data are presently available on actually delivered volumes of dialysate in CAPD patients. In fact there is concern that unless patients are fully compliant a lower-than-prescribed dose is delivered. If limited compliance to the CAPD prescription is common, it may explain in part the recent findings of worse outcomes for prevalent CAPD (who have been on therapy for various lengths of time) compared to hemodialysis patients (Bloembergen 1995a, 1995b, Habach). During 1996 the USRDS fielded a prospective national study of randomly selected patients new to ESRD treated by CAPD or hemodialysis (DMMS, Wave 2). Chapter IV of this report provides some initial results from this study.

The recent evidence of mortality risk by hemodialysis dose suggests that more attention needs to be placed also on the adequate prescription and delivery of peritoneal dialysis. The recent CANUSA study results suggest that more attention to the dialysis dose is imperative for improving outcomes for peritoneal dialysis (Canada-USA). A greater prescribed dose of peritoneal dialysis can be achieved by giving larger dialysate volumes in CAPD or by using CCPD or a combination of CAPD with CCPD. In addition to improving the PD dose that is prescribed by physicians, improving patient compliance with PD (which is not well studied) may increase survival. It is encouraging to see the recent increase in the use of CCPD (Figure III-4), since a higher dose is more easily achieved with this technique among large, functionally anephric patients. More detail about peritoneal dialysis therapy in 1996 is provided in Chapter IV.

Membrane Type in Hemodialysis

The USRDS Special Studies have also been instrumental in gathering information about the membrane type used in hemodialysis. There is a clear trend toward a decreased use of cellulose membranes and an increased use of synthetic membranes over time. Three USRDS studies allow assessment of recent changes in the types of membranes used in dialyzers among incident hemodialysis patients. Figure III-6 shows that in 1990 (Case Mix Adequacy Study), 70 percent of patients were being treated with cellulose membranes, versus 9 percent being treated with synthetic membranes. By 1996 (DMMS, Wave 2), only 22 percent of patients were treated with cellulose membranes, whereas 55 percent were treated with synthetic membranes. Results for 1993 (DMMS, Wave 1) showed an intermediary position. Thus, there has been a clear trend from cellulose membranes to modified cellulose and most pronounced to synthetic membranes. The reasons for this trend are unclear but may be in part resulting

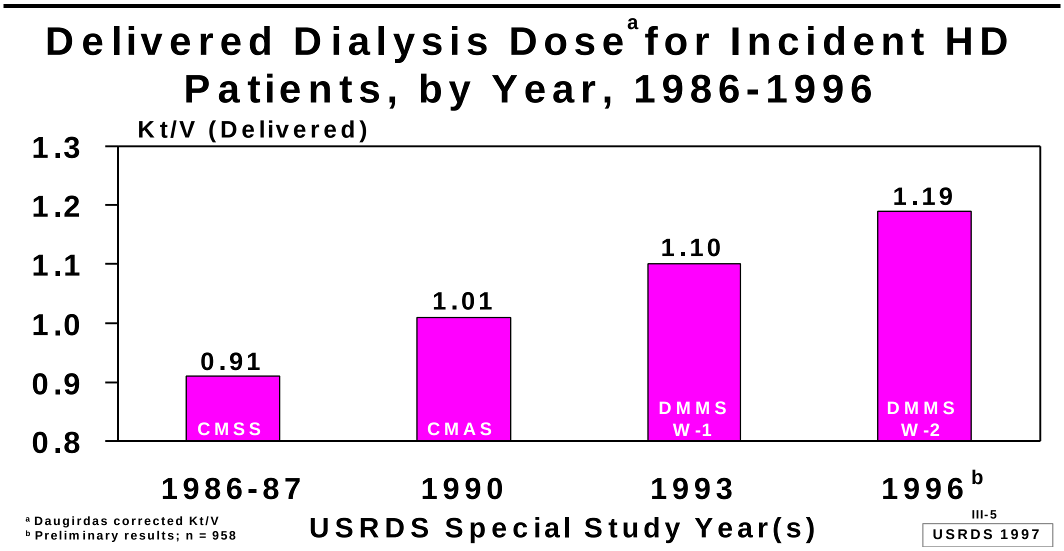

Figure III - 5

Dialysis dose in delivered Kt/V for incident hemodialysis patients by USRDS Special Study year, 1986-1996. Data from DMMS Wave 2 are preliminary. Source: Special analysis.

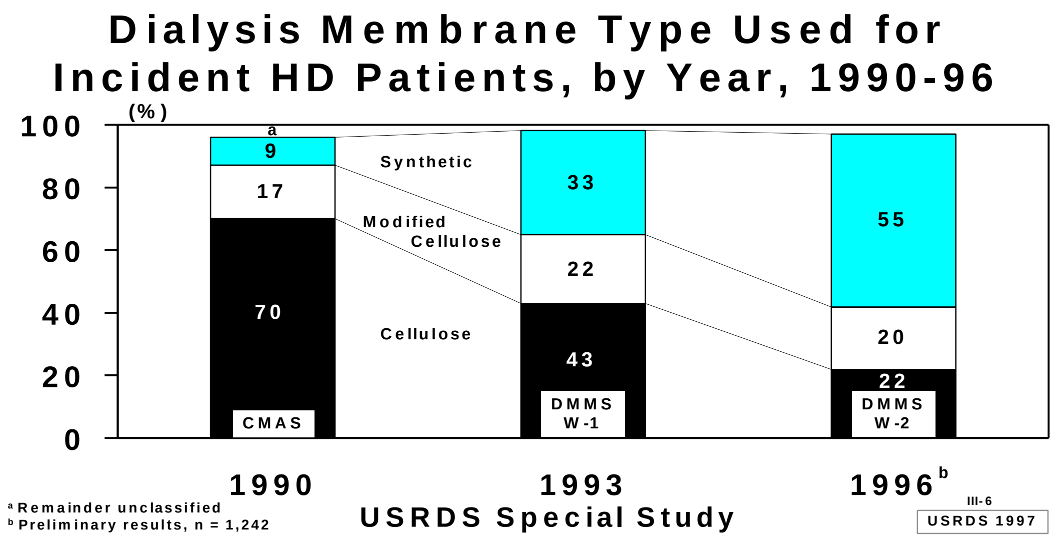

Figure III - 6

Percent distribution of membrane type used for incident hemodialysis patients by USRDS Special Study year, 1990-1996. Data for DMMS Wave 2 are preliminary. Source: Special analysis.

from a USRDS study of outcomes for patients treated with different membrane types which showed a correlation of cellulose membranes with higher mortality (Hakim). However, in this study it was not clear whether the membrane itself or other factors were responsible for this correlation.

Erythropoietin in Dialysis Patients

Recombinant human erythropoietin (rhEPO) became available in the United States in July 1989 and has been covered by Medicare since then. The number of dialysis patients receiving rhEPO has quickly increased from virtually zero in early 1989 to 90 percent in hemodialysis patients and near 60

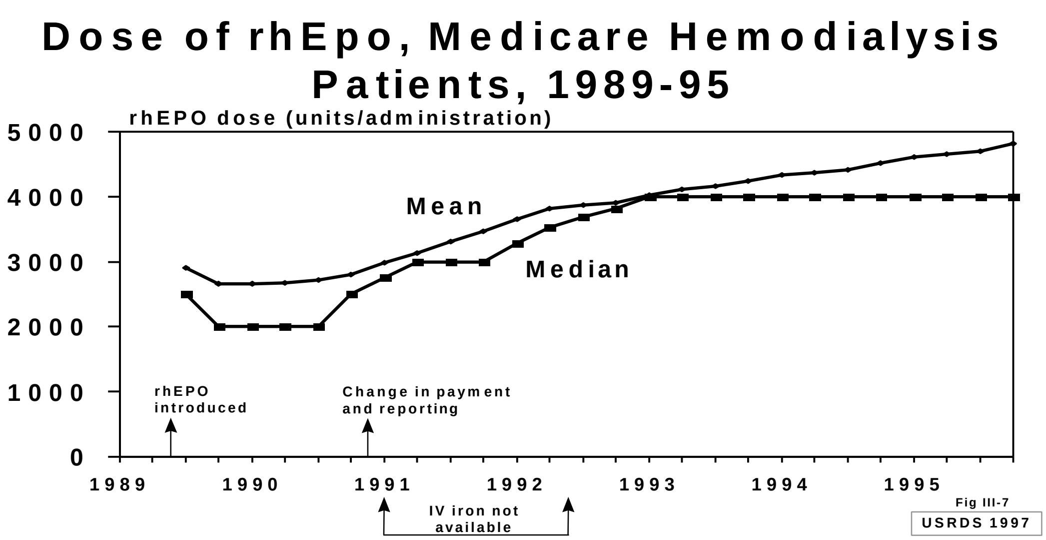

Figure III - 7

Dose of erythropoietin (rhEPO) among rhEPO-treated dialysis patients (hemodialysis and peritoneal dialysis) by calendar year and quarter, 1989-1995. Data are presented as mean and median units of rhEPO per administration. The approximate months during which parenteral iron was not available in the U.S. are indicated. Source: Special analysis.

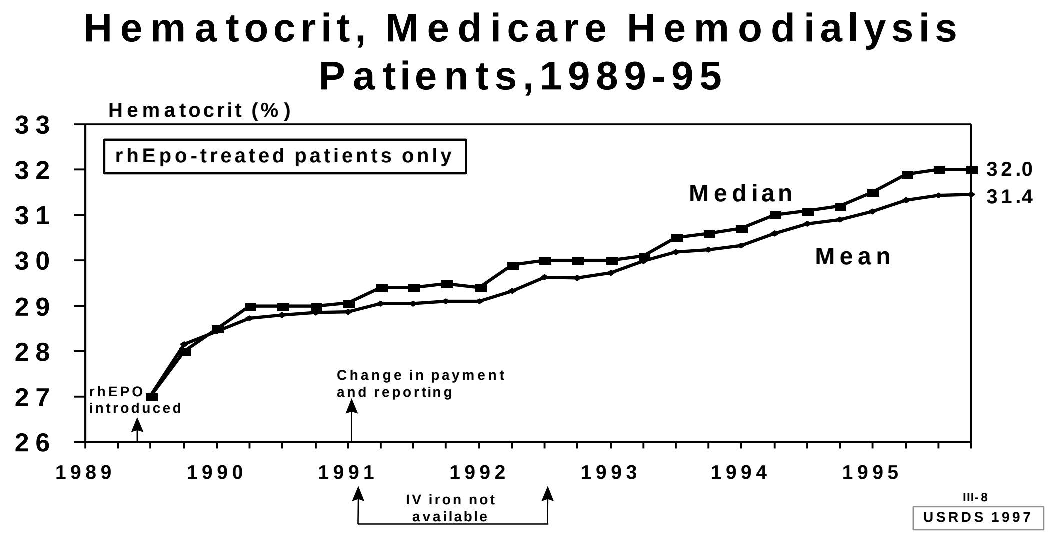

Figure III - 8

Percent hematocrit among rhEPO-treated patients (hemodialysis and peritoneal dialysis) by calendar year and quarter, 1989-1995. Data are presented as mean and median. The approximate months during which parenteral iron was not available in the US are indicated. Source: Special analysis.

percent in peritoneal dialysis patients at the end of 1995.

For patients receiving outpatient rhEPO, HCFA requires reporting of the rhEPO dose, number of administrations, and the hematocrit. Therefore, the time trend of rhEPO dose and hematocrit can be described for those Medicare dialysis patients who received outpatient rhEPO. Figure III-7 shows the mean and median rhEPO dose from 1989 to 1995. The mean and median hematocrit for the same time period is shown in Figure III-8. Overall, both the dose of rhEPO and the hematocrit have shown a steady increase over time. On January 1, 1991, the reimbursement for rhEPO by HCFA changed from a per administration to a per unit schedule. At the same time, however, parenteral iron became unavailable in the United States. Thus, although the dose of rhEPO was increasing, the response may have been blunted because of patients' iron status (Van Wyck). Figure III-8 supports this, showing a leveling off of mean hematocrit during the period when parenteral iron was unavailable, and a rise when it was reintroduced to the market. Iron deficiency continues to be a problem for a large fraction of hemodialysis patients according to the USRDS 1996 ADR and a USRDS study (Young). The mean and median hematocrit among rhEPO-treated patients has reached 31.4 and 32.0 percent, respectively, as of the last quarter of 1995.

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