Chapter III

Treatment Modalities for ESRD Patients

Renal replacement therapy for patients with ESRD includes several options, the main categories being renal transplantation, hemodialysis, and peritoneal dialysis. In this chapter hemodialysis (HD) is subdivided into center and home hemodialysis whereas peritoneal dialysis (PD) refers to predominantly continuous ambulatory PD (CAPD) and continuous cycling PD (CCPD) with a small subgroup of other PD. Renal transplantation may be from a living donor or a cadaveric donor and is discussed in more detail in Chapter VII.

Over time patients may move from one treatment modality to another, for example from CAPD to transplantation and, if the transplant fails, to hemodialysis. 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. More detail about hemodialysis treatment characteristics is provided in Chapter IV.

Treatment Modality Options

For patients with ESRD no treatment other than dietary was available until 1960. That year Belding Scribner treated the first patient for chronic renal failure. This became possible through the creation of a new vascular access, the external arterio-venous Scribner shunt. Before this time hemodialysis had been available only for short term therapy of acute renal failure (Peters). During the 1960’s, the biggest obstacle to chronic use of peritoneal dialysis was overcome by the development of the soft Tenckhoff catheter. Dacron cuffs on this catheter served to create a bacterial barrier. Renal transplantation had not been successful before this time except in identical twins (Murray) and became a reality during the 1960s through improved understanding of immunology and 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 three years) for immunosuppressive drugs after transplantation.

Over 250,000 ESRD patients are alive in the United States currently 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 they themselves report general satisfaction (Evans, 1985).

Renal transplantation: Renal transplantation from living related donors and from cadaveric donors became a clinical reality during the 1960s (Hamilton). Surgical technique had already been well developed before this time but immunological advances and new drugs modifying 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 has further expanded treatment prospects and graft survival (Merion; Kahan). 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 almost always 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, and whose circulation and respiration are maintained until organ removal (“harvesting”). Transplantation from a cadaver donor usually requires a prolonged waiting time, averaging close to two years, whereas transplantation from a living donor can be scheduled in advance and is more likely to be done as an initial or early 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 harvesting of the organ, presence or absence of panel reactive antibodies, patient demographic factors, and rejection episodes as well as immunosuppressive drug regimens. These factors are described further in Chapter VII.

Hemodialysis: Toxins and excess fluid are removed via extracorporeal circulation of blood through a dialyzer (artificial kidney). Treatments are most commonly scheduled three times weekly and last three to four 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, 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.

Peritoneal dialysis (PD): An alternative dialytic therapy, PD requires placement of a catheter into the abdominal cavity and repeated instillation and drainage of sterile dialysate. Equilibration of dialysate with plasma occurs during the dwell time, which usually lasts for several hours. When the dialysate is drained, toxins are removed in the (partially) equilibrated dialysate. 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 with typical dwell times of 4 to 8 hours 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, but CCPD use accounts for only one tenth of PD use. Combinations of CAPD and CCPD have recently been utilized, particularly in large patients with no residual renal function ( Diaz-Buxo). Intermittent PD (IPD) with frequent exchanges of dialysate, usually in thrice-weekly sessions lasting 10 to 12 hours is now rarely used. Several other variations of home PD have been described (Twardowski) but are not uniformly reported 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 a selection into PD therapy for two extreme patient groups, those 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, 1995). Recurrent peritonitis may be in part responsible for this observation. One may also speculate that a low delivered dose of CAPD may be responsible for 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 ESRD patients on December 31 is obtained from two sources: 1) the USRDS longitudinal patient treatment files ("data base") for all ESRD patients and 2) the year-end Facility Survey of all Medicare-approved dialysis units. Figure III-1 shows these counts for ten years, 1985 to 1994. 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 not only Medicare but also 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 clearly increased steadily as shown by the count of patients on each treatment modality. The only exception is the small home hemodialysis group, which experienced a 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 with over 60,000 patients. Transplant recipients who lost their transplant function and returned to dialysis are shown in the appropriate dialysis group in 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 (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 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 VII). 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. At the end of 1993, peritoneal dialysis patients accounted for 11 percent of all ESRD patients and 15.1 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 increase (Figure III-1). Since 1988, the percent distribution for all modalities has been remarkably stable. Only the small fraction of patients
utilizing home hemodialysis has shown a gradual decline since 1985.

There were two to three percent of patients for whom the modality could not be determined from available data or whose modality was changing at year end. In view of the small percentage their data are not included in Figure III-2. Additionally, patients who initiated dialysis therapy during the last two months of the most recent year, 1993, are automatically placed in this category according to definitions outlined in Chapter XII. Thus essentially all prevalent Medicare patients are accounted for in this analysis.

The distribution of patients on home hemodialysis

Figure III-2


Figure III-3

Percent distribution of prevalent dialysis patients on December 31, by type of dialysis and year, 1985-1994. Percentages include Puerto Rico and U.S. Territories. Medicare patients only. Source C.1
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 virtually 100 percent of all dialysis patients (note that figure III-2 indicated percentages of all ESRD patients, which included patients with functioning transplants). The use of CCPD has been increasing during the second half of the 1980s, and more steeply during the early 1990s. As of December 1993, CCPD accounted for approximately 2.4 percent of all dialysis and 15.6 percent of the peritoneal dialysis patients. These fractions reflect a clear increase for CCPD in recent years. Intermittent peritoneal dialysis, usually performed in a dialysis center, has been declining and is rarely used. Patients treated with other PD accounted for only 0.5 percent of all dialysis patients, and patients with unknown or uncertain dialysis accounted for 3 percent of all dialysis patients at the end of 1993. The fraction treated by CAPD has shown only a small increase since 1990.

To assess regional differences in the utilization of various treatment modalities, the percent of patients by modality and 18 geographic regions of the 18 ESRD Networks is provided for all ESRD patients alive at the end of 1991, 1992, or 1993 in Table III-1. Compared to the national summary data (labeled TOTAL), this table shows large variations for certain regions. The median age for the prevalent patients in 1993 (alive on December 31) varied by region from 52 to 58.9 for an overall median age of 54.7 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 accounted for 1.9 percent of dialysis patients and also had a wide range of utilization (1.1 to 3.5 percent). The utilization of CCPD did not appear to correlate with that of CAPD.

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**Table III-1**

<table>
<thead>
<tr>
<th>Network (State)</th>
<th>Total Count*</th>
<th>Functioning Transplant (% 0-64 only*)</th>
<th>Median Age*</th>
<th>Center Hemo</th>
<th>Home Hemo</th>
<th>CAPD</th>
<th>CCPD</th>
<th>Other PD/Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 1 (CT, MA, ME, NH, RI, VT)</td>
<td>9,678</td>
<td>46.2</td>
<td>57.7</td>
<td>77.5</td>
<td>1.0</td>
<td>14.7</td>
<td>3.0</td>
<td>3.9</td>
</tr>
<tr>
<td>No. 2 (NY)</td>
<td>15,626</td>
<td>31.3</td>
<td>56.7</td>
<td>80.3</td>
<td>1.1</td>
<td>13.6</td>
<td>1.6</td>
<td>3.5</td>
</tr>
<tr>
<td>No. 3 (NJ, Puerto Rico, Virgin Isl.)</td>
<td>9,873</td>
<td>27.9</td>
<td>56.3</td>
<td>78.7</td>
<td>1.0</td>
<td>13.6</td>
<td>3.0</td>
<td>3.7</td>
</tr>
<tr>
<td>No. 4 (DE, PA)</td>
<td>11,459</td>
<td>41.3</td>
<td>58.1</td>
<td>83.7</td>
<td>0.6</td>
<td>10.6</td>
<td>1.5</td>
<td>3.5</td>
</tr>
<tr>
<td>No. 5 (DC, MD, VA, WV)</td>
<td>13,448</td>
<td>33.6</td>
<td>55.8</td>
<td>82.5</td>
<td>0.7</td>
<td>10.8</td>
<td>1.1</td>
<td>4.8</td>
</tr>
<tr>
<td>No. 6 (GA, NC, SC)</td>
<td>18,233</td>
<td>27.4</td>
<td>55.2</td>
<td>82.0</td>
<td>0.5</td>
<td>11.5</td>
<td>3.5</td>
<td>2.6</td>
</tr>
<tr>
<td>No. 7 (FL)</td>
<td>12,366</td>
<td>34.7</td>
<td>58.9</td>
<td>85.5</td>
<td>0.5</td>
<td>9.0</td>
<td>2.6</td>
<td>2.4</td>
</tr>
<tr>
<td>No. 8 (AL, MS, TN)</td>
<td>11,882</td>
<td>32.9</td>
<td>55.2</td>
<td>83.8</td>
<td>1.7</td>
<td>10.0</td>
<td>1.9</td>
<td>2.6</td>
</tr>
<tr>
<td>No. 9 (IN, KY, OH)</td>
<td>16,726</td>
<td>43.7</td>
<td>55.3</td>
<td>73.7</td>
<td>0.6</td>
<td>17.4</td>
<td>1.5</td>
<td>6.8</td>
</tr>
<tr>
<td>No. 10 (IL)</td>
<td>10,365</td>
<td>40.4</td>
<td>55.7</td>
<td>82.3</td>
<td>0.6</td>
<td>10.3</td>
<td>1.7</td>
<td>5.1</td>
</tr>
<tr>
<td>No. 11 (MI, MN, ND, SD, WI)</td>
<td>16,347</td>
<td>50.4</td>
<td>54.6</td>
<td>74.9</td>
<td>1.0</td>
<td>18.3</td>
<td>1.5</td>
<td>4.3</td>
</tr>
<tr>
<td>No. 12 (IA, KS, MO, NE)</td>
<td>9,521</td>
<td>46.6</td>
<td>55.9</td>
<td>72.6</td>
<td>1.9</td>
<td>19.8</td>
<td>2.7</td>
<td>3.1</td>
</tr>
<tr>
<td>No. 13 (AR, LA, OK)</td>
<td>8,980</td>
<td>32.9</td>
<td>55.5</td>
<td>82.2</td>
<td>0.7</td>
<td>13.4</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>No. 14 (TX)</td>
<td>15,835</td>
<td>33.2</td>
<td>55.2</td>
<td>86.5</td>
<td>0.7</td>
<td>8.3</td>
<td>2.5</td>
<td>2.1</td>
</tr>
<tr>
<td>No. 15 (AZ, CO, NM, NV, UT, WY)</td>
<td>8,895</td>
<td>41.4</td>
<td>54.3</td>
<td>79.5</td>
<td>1.2</td>
<td>13.0</td>
<td>3.2</td>
<td>3.1</td>
</tr>
<tr>
<td>No. 16 (AK, ID, MT, OR, WA)</td>
<td>6,475</td>
<td>48.8</td>
<td>52.0</td>
<td>72.1</td>
<td>6.1</td>
<td>15.9</td>
<td>2.1</td>
<td>3.9</td>
</tr>
<tr>
<td>No. 17 (AS, N-CA, HI, CM, GU)</td>
<td>10,380</td>
<td>39.1</td>
<td>56.0</td>
<td>84.9</td>
<td>0.4</td>
<td>11.0</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>No. 18 (S-CA)</td>
<td>13,987</td>
<td>37.7</td>
<td>56.1</td>
<td>85.5</td>
<td>0.2</td>
<td>9.3</td>
<td>1.8</td>
<td>3.1</td>
</tr>
<tr>
<td>TOTAL</td>
<td>220,243</td>
<td>37.7</td>
<td>54.7</td>
<td>80.9</td>
<td>0.9</td>
<td>12.5</td>
<td>2.1</td>
<td>3.5</td>
</tr>
</tbody>
</table>

* for December 31, 1993 only
Source: Reference Tables C.7, C.8, special analysis
The fraction of patients treated by home hemodialysis shows an even greater variation by region than for other modalities, ranging from 0.2 to 6.1 percent of dialysis patients (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 as the numbers of living related and cadaveric renal transplants performed per year for 1984-94 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 steeply before 1986. Only a small increase could be observed between 1986 and 1990, and no increase since 1990. 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 1993 (Figure III-4) has serious implications, since it causes the waiting period for ESRD patients desiring a cadaveric transplant to increase even further. Thus, this figure clearly demonstrates the need for increased organ donation in the U.S.

The number of living donor transplants has increased only slightly, though steadily, during 1988 to 1994. Living donor transplantation seems to provide a superior patient and graft survival (Chapter VII). More details about the transplant process and the demographics of transplant donors and recipients is provided in Chapter VII.

**Utilization of Modalities by Patient Characteristics**

Wide variations in the utilization of the various treatment modalities existed by patient characteristics in 1992. Numerous factors influence the selection of treatment modality (Nissenson) and large differences are observed in international comparisons (Chapter XI). The demographics of access to transplantation has been well-studied (Gaylin; Webb) and is discussed further in Chapter VII.

Table III-2 describes the modality use by age, sex, race and cause of ESRD. Overall center hemodialysis was the most common form of ESRD therapy (59.0 percent) among prevalent patients at the end of 1993. Functioning renal transplant accounted for 27.3
percent, CAPD/CCPD for 10.9 percent and home hemodialysis for 0.2 percent of all ESRD patients treated at the end of 1993. Only 2.5 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 15.1 percent of dialysis, whereas all PD made up for 18.5 percent of all dialysis, when other PD/unknown modality was counted as PD.

By age group, younger patients had a much higher fraction of functioning transplants than older patients. Compared to 61.7 percent of ESRD patients with functioning transplants in the under 20 age group, there were 28.5 percent in the 45-64 age group and only to 5.1 percent in the 65 year and older group. The percentage using CAPD/CCPD appeared relatively stable across age groups ranging from 10.7 to 13.7 percent. Center hemodialysis was used infrequently in the pediatric ages accounting for 16.8 percent of patients under age 20. By contrast, the oldest age group (>65 years) was primarily (82.9 percent) treated by center hemodialysis. Home hemodialysis did not show much variation by age, except that children were underrepresented.

Racial differences in modality usage are apparent in this table. In the category of functioning transplant, Whites were over-represented and Blacks under-represented by a wide margin when compared to the average of 27.3 percent. The differences for the fractions with functioning transplants are likely due to differences both in transplantation rates (Gaylin) and in transplant graft and patient survival. Both issues are discussed in more detail in Chapter VII.

Home hemodialysis was used by 0.3 percent of dialysis patients overall according to the USRDS/HCFA database. The percentage reported for all patients (Medicare and non Medicare) according to the facility survey appears to be higher and unchanged from the previous year (2.4 percent). This discrepancy is currently being investigated.

Males had a higher percentage of functioning transplants (30.2 percent) compared to females (23.8 percent) which agrees with the finding of greater transplantation rates for males in multivariate analyses (Gaylin; Webb). Males and females utilized CAPD/CCPD at a nearly equal percentages of all dialysis patients (15.2 and 14.9, respectively).

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

<table>
<thead>
<tr>
<th>Patient Characteristic</th>
<th>Functioning Transplant</th>
<th>Center Hemo</th>
<th>Home Hemo</th>
<th>CAPD/CCPD</th>
<th>Other PD/Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Patients</td>
<td>27.3</td>
<td>59.0</td>
<td>0.21</td>
<td>10.9</td>
<td>2.5</td>
</tr>
<tr>
<td>Age 0-19</td>
<td>61.7</td>
<td>16.8</td>
<td>*</td>
<td>13.7</td>
<td>7.7</td>
</tr>
<tr>
<td>Age 20-44</td>
<td>48.2</td>
<td>37.9</td>
<td>0.19</td>
<td>10.9</td>
<td>2.8</td>
</tr>
<tr>
<td>Age 45-64</td>
<td>28.5</td>
<td>56.8</td>
<td>0.21</td>
<td>11.1</td>
<td>3.4</td>
</tr>
<tr>
<td>Age 65+</td>
<td>5.1</td>
<td>82.9</td>
<td>0.24</td>
<td>10.7</td>
<td>1.0</td>
</tr>
<tr>
<td>Male</td>
<td>30.2</td>
<td>56.4</td>
<td>0.20</td>
<td>10.6</td>
<td>2.5</td>
</tr>
<tr>
<td>Female</td>
<td>23.8</td>
<td>62.1</td>
<td>0.22</td>
<td>11.3</td>
<td>2.5</td>
</tr>
<tr>
<td>Native American</td>
<td>23.1</td>
<td>65.4</td>
<td>*</td>
<td>10.3</td>
<td>0.7</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>27.4</td>
<td>60.8</td>
<td>0.19</td>
<td>10.3</td>
<td>1.3</td>
</tr>
<tr>
<td>Black</td>
<td>14.1</td>
<td>74.7</td>
<td>0.18</td>
<td>8.8</td>
<td>2.2</td>
</tr>
<tr>
<td>White</td>
<td>34.1</td>
<td>51.2</td>
<td>0.23</td>
<td>12.1</td>
<td>2.4</td>
</tr>
<tr>
<td>Diabetes</td>
<td>19.1</td>
<td>67.5</td>
<td>0.18</td>
<td>12.0</td>
<td>1.2</td>
</tr>
<tr>
<td>Hypertension</td>
<td>13.9</td>
<td>74.1</td>
<td>0.22</td>
<td>10.7</td>
<td>1.0</td>
</tr>
<tr>
<td>Glomerulonephritis</td>
<td>42.6</td>
<td>44.5</td>
<td>0.22</td>
<td>11.4</td>
<td>1.3</td>
</tr>
<tr>
<td>Cystic Kidney Disease</td>
<td>44.2</td>
<td>43.1</td>
<td>0.21</td>
<td>11.2</td>
<td>1.2</td>
</tr>
<tr>
<td>All Other</td>
<td>34.5</td>
<td>49.2</td>
<td>0.23</td>
<td>9.8</td>
<td>6.2</td>
</tr>
</tbody>
</table>

** Percentages add across to ~ 100
* Cell with a count of less than 10
Source: Reference Tables C5,C6
much higher for patients with glomerulonephritis and cystic kidney disease (43 - 44 percent). By contrast, prevalent patients with diabetes or hypertension as cause of ESRD had only 19 and 14 percent with functioning transplant, respectively. The use of CAPD/CCPD appears to be similar by diagnosis group in this table. However when re-analyzed as a fraction of only dialysis patients, it was relatively high in the glomerulonephritis and cystic disease groups (20 percent) and relatively low in the hypertension group (12.4 percent).

**Prescription for Hemodialysis**

Three Special Studies on random samples of U.S. hemodialysis patients have been performed by the USRDS: The Case Mix Severity Study, Case Mix Adequacy Study and the first wave of the Dialysis Morbidity and Mortality Study (DMMS). Their respective study start dates were 1986-87, December 31, 1990 and December 31, 1993. Each study collected information for a random sample of near 6,000 dialysis patients. Analyses of these data have been provided in previous USRDS Annual Data Reports, specifically in 1992 regarding the Case Mix Severity Study and the 1995 report on the Case Mix Adequacy Study. The prescription of hemodialysis has been increasing according to comparisons between the 1990/91 and the 1993/94 samples of the two recent USRDS studies. There has been clear documentation that the dose of dialysis in the United states has been relatively low as compared to European data (Held, 1994b) and that a higher dose correlates with lower mortality risk (Owen, Held 1996). Chapter IV of the present report provides the initial analytical results of the DMMS Wave -1 regarding dialysis dose and other treatment parameters.

**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. Thus, a daily dialysate volume of less than 8 liters was prescribed in 27 percent of patients (USRDS 1992a). Although these data were obtained early in CAPD therapy (at day 30 of ESRD), these data 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 the 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 is fielding a prospective national study of randomly selected patients new to ESRD treated by CAPD or hemodialysis. This study will provide more current information of dialysis prescription and outcomes in addition to detailed information on comorbid status, treatment selection, quality of life and rehabilitation.

As the hemodialysis dose increased in recent years, more attention needs to be placed on the adequate prescription (and delivery, i.e. compliance) of peritoneal dialysis. A greater dose of peritoneal dialysis can be achieved by giving larger dialysate volumes or by using CCPD or a combination of CAPD with CCPD. It is encouraging to see the recent increase in the use of CCPD, but the recent CANUSA study results suggest that more attention to the dialysis dose is imperative for peritoneal dialysis (Canada-USA) as it has been documented for hemodialysis. More detail about hemodialysis is provided in Chapter IV.

**Erythropoietin in Dialysis Patients**

Recombinant human erythropoietin (EPO) became available in the U.S. in July 1989 and has been a Medicare outpatient service since. The number of dialysis patients receiving EPO has quickly increased from virtually zero in early 1989 to 92 percent in hemodialysis patients and near 60 percent in peritoneal dialysis patients at the end of 1994.

For patients receiving outpatient EPO, HCFA requires reporting of the EPO dose, number of administrations and the hematocrit. Therefore, the time trend of EPO dose and hematocrit can be described for those Medicare dialysis patients who received outpatients EPO. Figure III-5 shows the EPO dose per administration as mean and median from 1989 through 1994 and similar data for the mean and median hematocrit. Overall, both the dose
of EPO and the hematocrit have shown a steady increase over time. On January 1, 1991 the reimbursement for EPO by HCFA changed from a per administration to a per unit schedule. At the same time the response to EPO therapy may have been limited by the fact that parenteral iron was not available in the U.S. (Van Wyck). As shown in Figure III-5, the hematocrit appears to have increased more steeply after a new preparation of parenteral iron became available. The mean and median hematocrit among EPO treated patients has reached 31 and 31.4 percent, respectively, as of the last quarter of 1994.

More detail about anemia, iron status and EPO has been learned from the DMMS-1 study of a random sample of hemodialysis patients. Some of the early results from this USRDS study are presented in Chapter IV.

**References:**


