

Chapter IV

The USRDS Dialysis Morbidity and Mortality Study (Wave 1)

The USRDS Dialysis Morbidity and Mortality Study is an observational study in which demographic, comorbidity, laboratory, treatment, socioeconomic and insurance data are collected for a large random sample of U.S. dialysis patients, using the patient's dialysis records. The plans for this study include 4 phases ("waves") of data collection on 6000 ESRD patients each in Waves I, III and IV and 4,500 patients in Wave II, for a total sample of 22,500 patients over 3 years. Waves I, III and IV are each historical prospective studies in which data are collected for patients receiving in-center hemodialysis on 12/31/93. In each of these "waves", data are abstracted from the patient's medical record with patient status followed from 12/31/93 through the earliest of date of data abstraction, death, transplant, change in modality or transfer to another facility. Wave II, which begins in 1996, is a true prospective study of incident hemodialysis and peritoneal dialysis patients for 1996.

Each "wave" includes a data collection instrument for collecting "core" data which will allow collection of a consistent set of fundamental data for research questions that require a large sample size. These include questions related to adequacy of dialysis, dialyzer membranes, and dialyzer reuse. The "core" data will also be used to develop a "comorbidity infrastructure" which will be useful for the investigation of many other important research questions. In addition, Waves I and II both include a "non-core" component designed to address additional research questions that require smaller sample sizes. For example, in addition to the "core" data collected on all patients in Wave I, completed in August 1995, data were also collected on anemia, nutrition, and vascular access on subsamples of the patients included in the "core" component. This chapter reports descriptive analyses of data from Wave I of the

USRDS Dialysis Morbidity and Mortality Study (DMMS-1).

Methods

Patient Sample

A sample of dialysis units (N=550) was randomly selected for Wave I of the DMMS from the Master List of Medicare Approved Dialysis Facilities as of December 31, 1993. This Master List exists as part of the annual Medicare Survey of Dialysis Facilities. The sample of patients selected for Wave I of the DMMS was selected from a national census of hemodialysis patients as of December 31, 1993. This census of hemodialysis patients (Medicare and non-Medicare) was provided by the 18 ESRD Networks. Patients were excluded if they were less than 15 years of age, in training for any self care treatment, or receiving CAPD, home hemodialysis or other dialysis on 12/31/93. From the 550 selected facilities, a total of 6300 in-center hemodialysis patients were selected for inclusion in the study (to achieve a sample size goal of 6000 patients, assuming a 95 percent response rate) in the following manner: To increase the number of incident (new) patients included, all hemodialysis patients starting therapy in December of 1993 were included (N=1100 expected). The remaining 5200 patients were randomly selected from the remaining eligible patients receiving hemodialysis on December 31, 1993 at the selected facilities. Approximately one in five patients were selected from each facility to obtain the desired sample size. Of these, it was expected that approximately 25 percent would have started hemodialysis in 1993 (also labeled "incident") and the remainder would have started in prior years (labeled "prevalent").

Data Collection

The “core” set of data questions was administered to all patients in the sample. Patients identified as incident in 1993 (all patients starting hemodialysis in December 1993 in addition to a random sample of patients starting ESRD treatment in the remaining months of 1993 and on hemodialysis on December 31, 1993) were included in the “non-core” study of vascular access. A random selection of one half of the overall sample of 6300 patients was drawn for the nutrition and anemia studies. In addition to the patient-specific data, a questionnaire was also completed for each dialysis facility in the sample, allowing the collection of data on reuse practices, water treatment, methods used to calculate dose of dialysis, etc.

The data collection instruments were developed by the USRDS Coordinating Center and tested by the ESRD Networks. A pre-test was conducted in the Fall of 1994. ESRD Networks 1, 3, 4, 7, 8, and 13 volunteered to participate in the pre-test and recruited a total of 25 dialysis units for participation. The pre-test focused on the feasibility of collecting the data and the overall quality of the data collected. Pre-test data were compared to data from the USRDS Case Mix Adequacy Study. Copies of the data collection forms are in Appendix B of this report.

Wave I of the DMMS began in March of 1995 and data continued to be collected through July 31, 1995. Data were abstracted from patient medical records by dialysis facility personnel. Completed questionnaires were returned to the ESRD Networks where a “quality check” of six items was performed on each questionnaire (Height, weight, BUN, hematocrit, prescribed dialysis, and re-use status were reviewed for whether or not these values fell within an appropriate range). The completed questionnaires were then sent on to the USRDS Coordinating Center.

Data Validation

A Data Validation Study of the Wave I data was conducted in August and September of 1995. The data were collected by Network personnel using the same patient records used to abstract the data for Wave I of the DMMS. The data collected included, for each patient selected, 22 items from the Core Questionnaire, 4 items from the Vascular Access Questionnaire, and 4 items from the Anemia and Nutrition Questionnaires. The sample of patients for the Data Validation Study was a 1000 patient subsample of DMMS Wave I. Each Network’s subsample was drawn such that 80 percent of the patients were dialyzed within 110 miles of the Network Office since Network personnel needed to

travel to the dialysis units and abstract the data from the patient records. The remaining 20 percent were dialyzed more than 110 miles from the Network Office. The data from the Data Validation Study have been keypunched and preliminary analyses have been conducted. These analyses were still underway and will be reported later during 1996.

Analysis

This chapter includes univariate statistics for data pertaining to the delivery of dialysis generated from Wave 1 of the DMMS. No adjustments have been made for demographic, comorbid or treatment parameters, and therefore the data presented is to be considered only descriptive in nature.

Results

“Core” data were collected on 5670 in-center hemodialysis patients who were alive on December 31, 1993, (response rate of 90 percent, 95 percent of expected sample). The response rate was somewhat lower than expected as Network 10 facilities were unable to participate (N=281). For the remaining 449 patients sampled but not included in the study, data forms were either not returned or invalid due primarily to inconsistencies in modality or facility assignment in the Network ESRD patient census. Of these patients, 38.4 percent started dialysis in 1993 (classified as “incident”) and the remainder were classified as “prevalent”. The vascular access “non-core” component was completed for 1997 patients. The anemia and nutrition components were completed for 2613 and 2523 patients, respectively.

Dose of Hemodialysis

Analyses pertaining to dose of dialysis were limited to patients treated for ESRD for more than one year (prevalent). This selection was done to minimize the role of residual renal function on dialysis prescription under the assumption that after more than one year of dialysis, residual renal function is minimal or absent. Analyses were also limited to those receiving 3 dialysis sessions per week (unless otherwise indicated) and to patients dialyzed using bicarbonate dialysate (N=3072).

For this analysis, delivered dose of dialysis was measured as Kt/V and was calculated from the following formula:

$$\text{Delivered Kt/V} = \ln(R-0.008*t) + (4-3.5R)*UF/W$$

(Daugirdas, 1993)

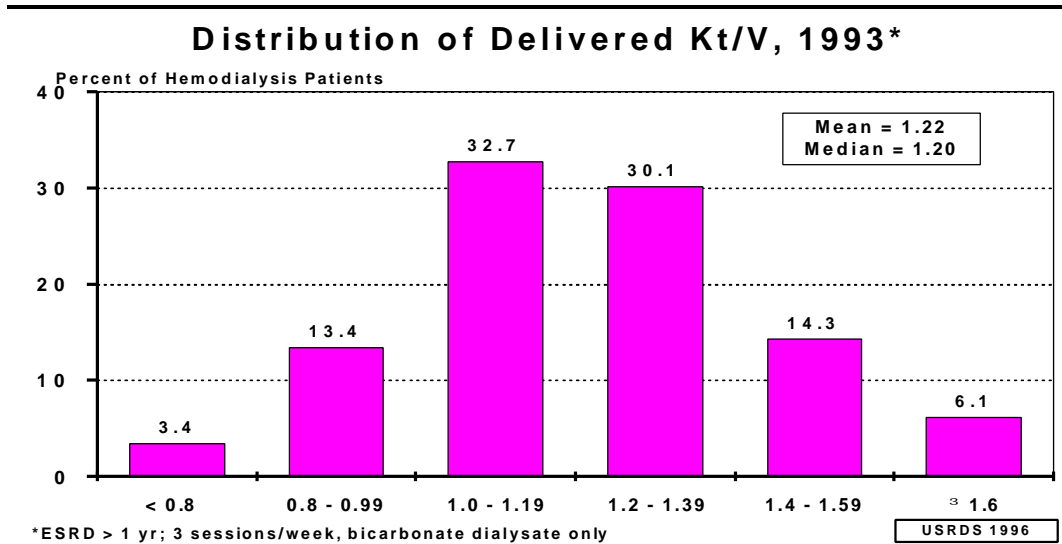


Figure IV-1

Distribution of patients by delivered dose of dialysis as measured by Daugirdas corrected Kt/V for center hemodialysis patients on ESRD treatment for more than one year as of December 1993. Only patients on a thrice weekly dialysis schedule and with bicarbonate dialysate are included

where $R = \text{post-dialysis} / \text{pre-dialysis}$ blood urea nitrogen, $t = \text{dialysis hours}$, $UF = \text{pre-post dialysis weight (change in weight occurring during the dialysis session)}$ and $W = \text{postdialysis weight}$. The mean value of several monthly Kt/V readings over a 6 month period (July to December 1993) for each patient was used. Urea reduction ratio (URR), an alternate measurement of dose of dialysis, was also evaluated.

Among the facilities sampled for this study, the majority had in place a policy to draw the post dialysis urea sample immediately following or within one minute of termination of dialysis. Therefore the calculated Kt/V values likely represent the so-called "single-pool" kinetics and do not account for access or cardiopulmonary recirculation or rebound, and may be an overestimate of the true Kt/V in some patients.

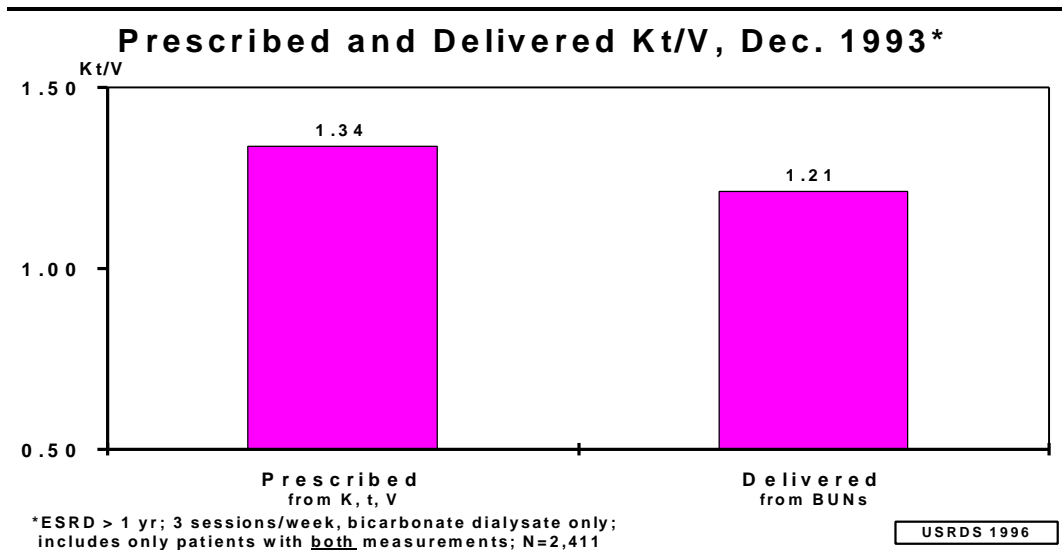


Figure IV-2

Mean prescribed and delivered dose of hemodialysis among 1993 DMMS Wave I patients for whom both measures could be calculated. Only patients with ESRD for more than one year, on a thrice weekly dialysis schedule and with bicarbonate dialysate are included.

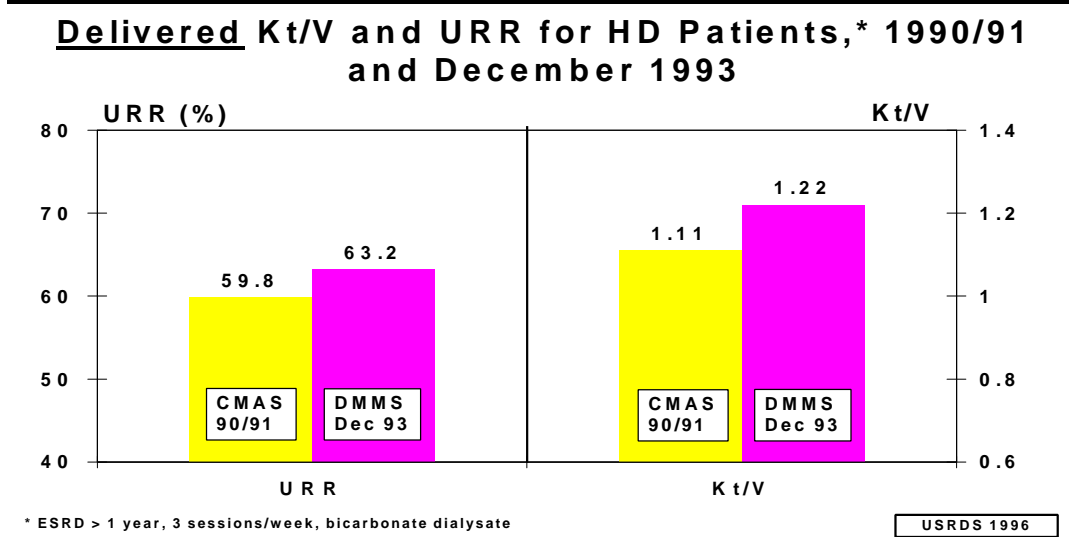


Figure IV-3

Mean delivered dose of hemodialysis according to urea reduction ratio (URR) and Daugirdas corrected Kt/V for 1990/91 CMAS and December 1993 DMMS Wave I.

Measured residual renal function was not available in this study but it was assumed to be minimal or absent after more than one year of ESRD. Prescribed dose of dialysis was derived from the manufacturer’s specifications of the prescribed dialyzer, prescribed dialysis time and blood flow, an assumed dialysate flow of 500 ml/min and estimated patient volume based on the patient’s height, weight and gender.

Between July and December 1993, the mean delivered Kt/V value was 1.22. The mean URR, an alternate measure of dose of dialysis, was 63.2 percent. Figure IV-1 shows the distribution of dose of dialysis as measured by delivered Kt/V among this national random sample of in-center dialysis patients. Approximately 30 percent of patients were receiving a delivered Kt/V of 1.2 to <1.4, whereas 14 percent received a Kt/V of 1.4 to <1.6 and 6 percent of patients were receiving a Kt/V of 1.6 or greater. However, approximately 50 percent of patients were receiving a Kt/V of less than 1.2, the minimum recommended delivered dose suggested by a number of groups (NIH Consensus Statement 1993; Kopple 1994) and almost 17 percent were receiving a delivered Kt/V of less than 1.0.

Trends

These data reflect an increase in the delivered dose of dialysis over recent years on a national level, compared with the two prior USRDS national studies of randomly selected hemodialysis patients, the Case Mix Severity Study (CMSS) and the Case Mix Adequacy Study (CMAS). Although not entirely

comparable to the present study as it included only new (incident) dialysis patients, the CMSS found an average prescribed initial Kt/V of 1.0 in patients starting dialysis in 1986-1987 (Held, Carroll 1994). In that study, delivered dose was also shown to be even lower than prescribed. The DMMS Wave 1 “core”, included a random sample of hemodialysis patients prevalent on December 31, 1990. Figure IV-2 compares the prescribed and delivered dose of dialysis for the DMMS-1 study, only among patients for whom both prescribed and delivered Kt/V could be calculated (note: for this reason, values are slightly different than in other figures). The mean delivered Kt/V of 1.21 was substantially lower than the mean prescribed Kt/V of 1.34.

As both Kt/V and URR are either totally or mostly derived from pre and post dialysis BUN, not surprisingly, there has been shown to be close correspondence between these two measures (Held 1996). Figure IV-3 compares both the delivered Kt/V and URR for the 1990/91 Case Mix Adequacy and DMMS-1 studies. Delivered dose of dialysis has increased from a mean Kt/V of 1.11 to 1.21 and from a mean URR from 59.8 percent to 63.2 percent.

Concern about the high mortality rate among the U.S. hemodialysis patient population relative to patients in other countries was first raised in the late 1980’s (Held 1990). A strong relationship of lower mortality associated with higher doses of dialysis has been shown by a number of studies (Owen 1993, Collins 1991, Schleifer 1991, Acchiardo 1992; Hakim

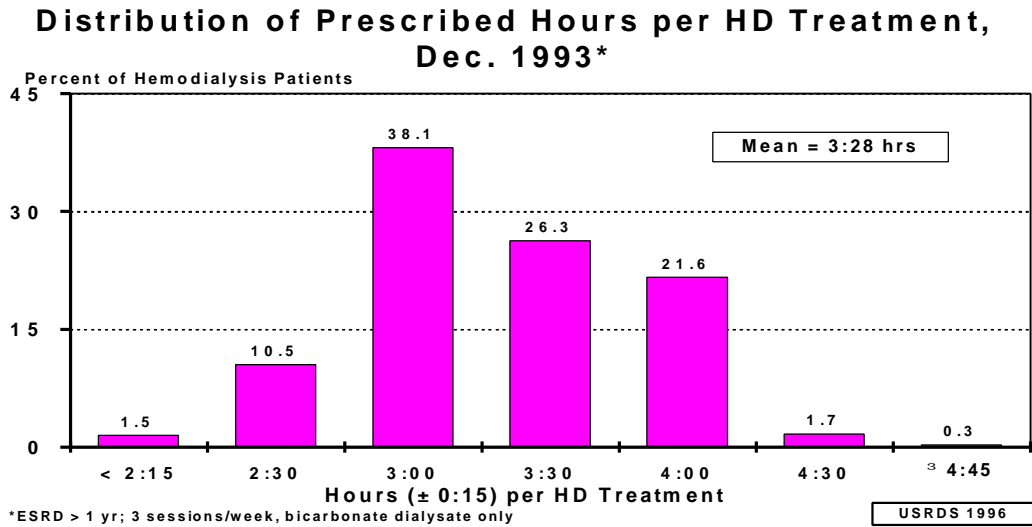


Figure IV-4

Distribution of patients by prescribed hours per hemodialysis treatment session in December 1993. Only patients with ESRD for more than one year, on a thrice weekly dialysis schedule and with bicarbonate dialysate are included.

1994; Held 1996). These studies may have led to both increases in the minimum recommended dose and the actual delivered dose over this time period.

Length of Treatment

Figure IV-4 shows the frequency distribution of hours prescribed per hemodialysis session in the DMMS national sample, among patients dialyzed 3

sessions per week. The largest percentage of patients was prescribed 3 hours of treatment (38 percent), and the second largest 3½ hours (26 percent). Approximately 24 percent of patients were prescribed 4 hours or more. Of these, only 2 percent were prescribed more than 4 hours. Twelve percent of patients were prescribed 2.5 hours or less. The mean number of hours per treatment was approximately 3½

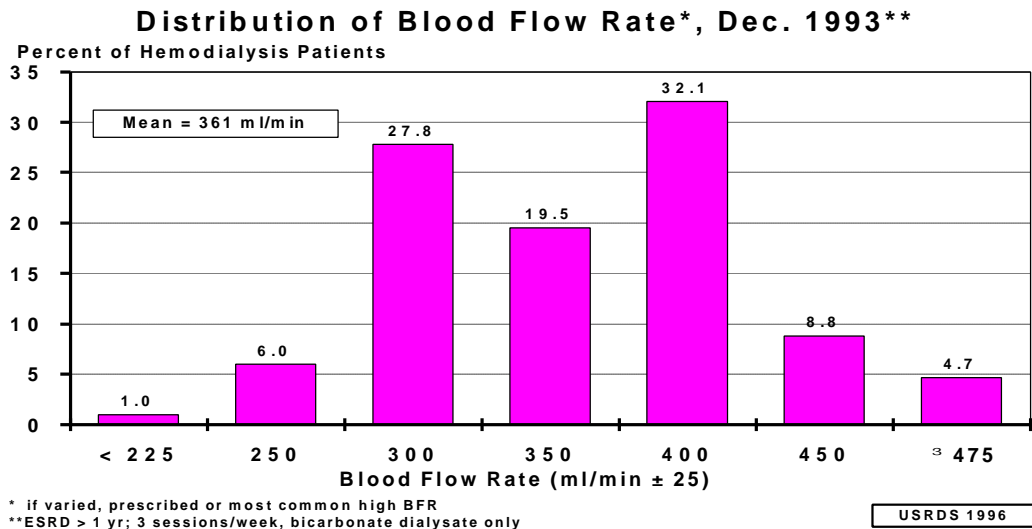


Figure IV-5

Distribution of patients by blood flow rates in December 1993. When blood flow varied either the prescribed or the most common "high" rate is recorded. Only patients with ESRD for more than one year, on a thrice weekly dialysis schedule and with bicarbonate dialysate are included.

Data used to Calculate Dose of Dialysis among U.S. Dialysis Facilities, 1993

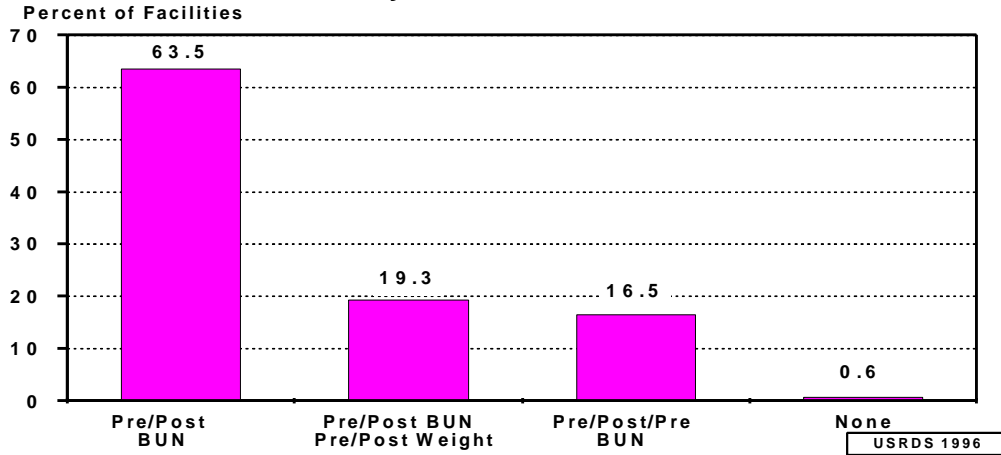


Figure IV-6

Distribution of facilities according to data used to calculate the delivered dose of hemodialysis in December 1993, based on a random sample of 550 hemodialysis facilities.

hours. In a previous study Held and coworkers have reported that the duration of dialysis was shorter in the United States than in Europe and Japan (Held 1992).

Blood Flow Rate

The distribution of blood flow rate (BFR) among the patient sample is shown in Figure IV-5. For each patient, the BFR was recorded as of December 1993. If the BFR varied, the prescribed or most common

“high” BFR was abstracted. The most commonly reported blood flow rate was 400 +/- 25 ml/min (32 percent) followed by 300 +/- 25 ml/min (28 percent) and 350 +/- 25 ml/min (19.5 percent). Combined, approximately 80 percent of patients were prescribed blood flow rates of 300-400 +/- 25 ml/min. Seven percent of patients were prescribed rates of 275 ml/min or less and 13.5 percent were prescribed greater than 425 ml/min. The mean blood flow rate

Timing of Post Dialysis BUN Sample among U.S. Dialysis Facilities, Dec 1993

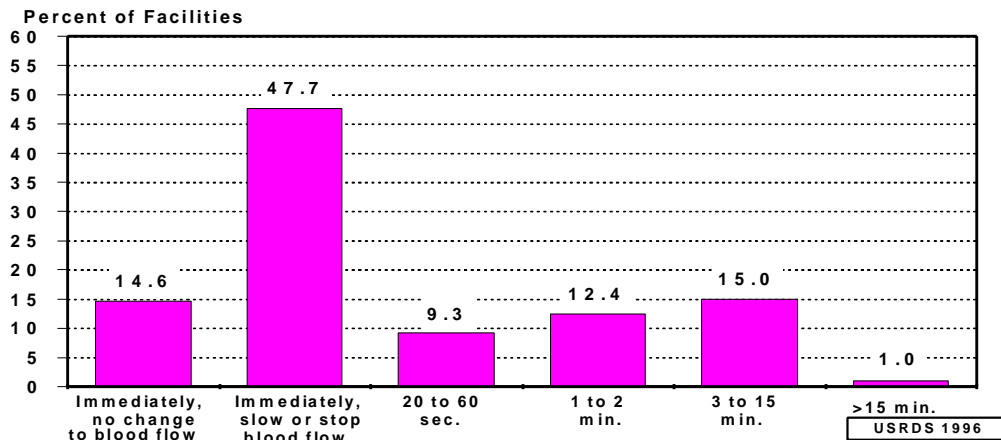


Figure IV-7

Distribution of facilities according to the timing of the post dialysis BUN sample for calculating the delivered dose of hemodialysis in December 1993, based on a random sample of 550 hemodialysis facilities.

Dialyzer Membrane Classification, 1993

Unmodified Cellulose - 41.8%

Cellulose - 37.2
 Cuprophane - 3.3
 Saponified Cellulose - 1.2
 Cuprammonium Rayon - 0.1

Modified Cellulose - 22.4%

Cellulose acetate - 18.2
 Cellulose triacetate - 2.0
 Modified cellulose acetate - 1.2
 Hemophan - 0.9
 Cellulose diacetate - 0.1

Synthetic - 35.7%

Polysulfone - 35.1
 AN69 - 0.4
 PMMA - 0.2

Dialyzer Membrane Classification, 1993, Medicare and Non-Medicare patients. From the USRDS Dialysis Morbidity and Mortality Study.

Table IV-1

was 361 ml/min.

Number of Sessions per Week

Among all prevalent patients using bicarbonate dialysate, 95.5 percent of patients were dialyzed 3 sessions per week, 4.1 percent were dialyzed twice weekly, 0.1 percent were dialyzed once weekly and 0.2 percent were dialyzed 4 times weekly.

Dialysis Dose Measurement Practices

Facility questionnaires which were completed for all dialysis units in which patients were sampled in this

study also provided information regarding policies and practices for measurement of dose of dialysis. The type of data used to calculate the dose of dialysis among U.S. facilities in 1993 is shown in Figure IV- 6. Kt/V or urea reduction ratio (URR) was calculated using only a pre- dialysis and post- dialysis blood urea nitrogen (BUN) in 63.5 percent of facilities. Kt/V was calculated from a pre- and post- dialysis BUN and a pre- and post dialysis weight in 19.3 percent of facilities and Kt/V was calculated from a pre-, post- and pre- (next session) dialysis BUN in 16.5 of units. Only 0.6 percent of units reported that neither Kt/V or URR were calculated.

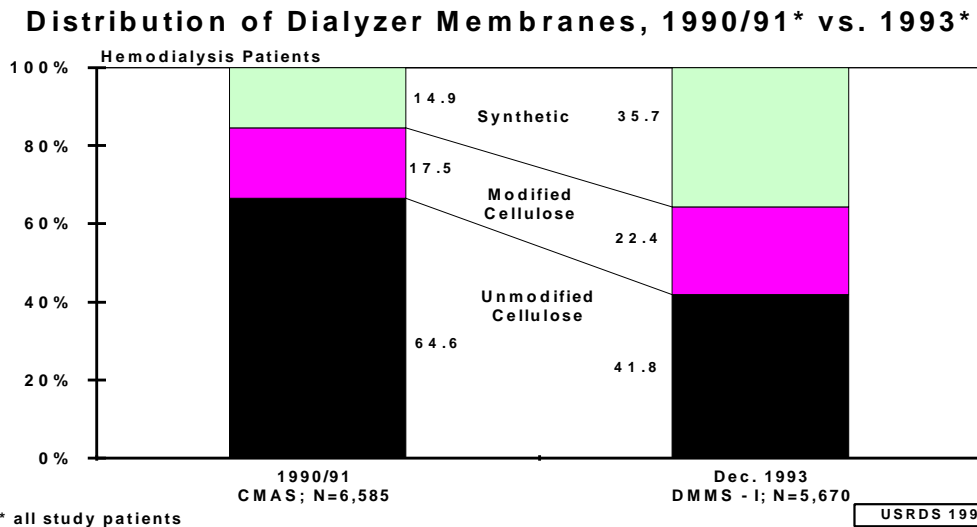


Figure IV-8

Distribution of dialysis patients by hemodialyzer membrane category for two study samples, 1990/91 and December 1993. No patient exclusions.

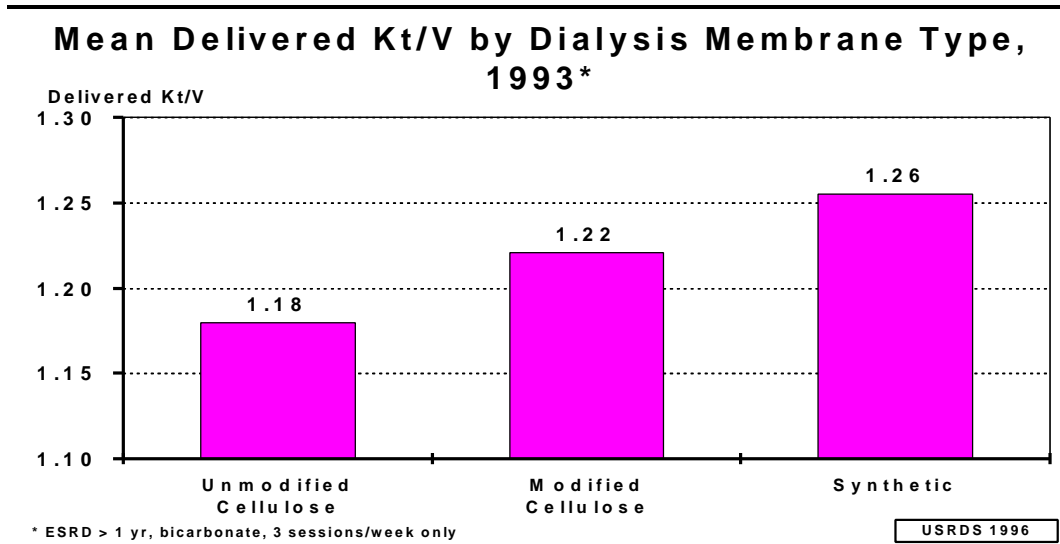


Figure IV-9

Mean delivered Kt/V by hemodialyzer membrane category in December 1993. Only patients with ESRD for more than one year, on a thrice weekly dialysis schedule and with bicarbonate dialysate are included.

U.S. dialysis facilities policies regarding the timing of the post dialysis BUN sample are presented in Figure IV-7. Approximately fifteen percent of units obtained the post dialysis BUN sample immediately at the end of dialysis without slowing the blood flow, 48 percent immediately at the end of dialysis after slowing or stopping the blood flow, and 9 percent drew the sample between 20-60 seconds after the end of dialysis.

In only 28 percent was the policy to wait at least one minute (1-2 minutes = 12 percent, 3-15 minutes = 15 percent, and greater than 15 minutes = 1 percent). Slowing the blood pump and waiting for at least 1-2 minutes has been recommended by some authors to obtain a more accurate Kt/V (Daugirdas 1994; Daugirdas 1995). On the other hand, the majority of available studies evaluating Kt/V and its association with clinical outcomes have been derived from data based on post dialysis BUN samples taken within one minute of the end of dialysis.

Membrane

The dialyzers in use can be classified as unmodified cellulosic, modified cellulosic or synthetic (Table IV-1). The most common modified cellulose

membrane was cellulose acetate and the most common synthetic membrane was polysulfone.

Figure IV-8 shows the distribution of dialyzer membranes for the 1990/91 cohort (CMAS) and the 1993 cohort (DMMS-1) of prevalent hemodialysis patients treated with bicarbonate dialysate. There has been a substantial reduction in the use of unmodified cellulosic membranes over this time period with a simultaneous increase in the use of the remaining membrane types. In 1990/91, 64.6 percent of patients were dialyzed using an unmodified cellulose membrane whereas in 1993 this figure had decreased to 41.8 percent. The use of modified cellulosic membranes increased from 17.5 to 22.4 percent of the total. Of particular note, the use of synthetic membranes more than doubled, from 14.9 to 35.7 percent.

Figure IV-9 shows that the mean delivered Kt/V varied by membrane type among prevalent patients dialyzed 3 times weekly with bicarbonate dialysate in the DMMS-1. The mean delivered Kt/V was 1.18 among patients dialyzed with unmodified cellulose membranes, 1.22 for patients dialyzed with modified cellulose membranes and 1.26 for patients dialyzed with synthetic membranes.

Dialyzers

The distribution of dialyzers in use in December 1993 among the patients sampled is shown in Table IV-2. This analysis corrected for the over-sampling of

patients starting ESRD therapy in December 1993 and is therefore representative of U.S. hemodialysis patients treated on December 31, 1993. Dialyzers used less frequently than in 1 percent of patients are not shown.

**Distribution of Dialyzers in Use
1993¹**

MODEL	PERCENT OF TOTAL PATIENTS ²	CUMULATIVE PERCENT
FRESENIUS F80	19.8	19.8
TERUMO ICL-C121L	7.2	27.0
TERUMO ICL-T175L	7.1	34.1
BAXTER CA 110	6.0	40.1
FRESENIUS F8	5.5	45.6
BAXTER CA 210	5.3	50.9
FRESENIUS F60	4.8	55.7
TERUMO ICL-C101L	3.2	58.9
BAXTER CA 170	2.5	61.4
BAXTER CA 150	2.2	63.6
TERUMO ICL-M151L	2.2	65.8
ASAHI AM-SD 65H	2.0	67.8
BAXTER CT 190G	1.8	69.6
FRESENIUS F5	1.8	71.4
FRESENIUS F6	1.8	73.2
BAXTER CF 2308	1.7	74.9
BAXTER CF 25	1.7	76.6
TERUMO ICL-T220L	1.4	78.0
BAXTER CF 1511	1.3	79.3
ALTHIN CD SCE 135	1.2	80.5
BAXTER CF 23	1.1	81.6
NMC FOCUS 120	1.1	82.7
ALTHIN CD MCA 160	1.0	83.7
BAXTER CA 90	1.0	84.7
OTHER ³	15.3	100.0

¹From the USRDS Dialysis Morbidity and Mortality Study - Wave 1,

²All patients, n = 5670

³Each <1.0%

Table IV - 2

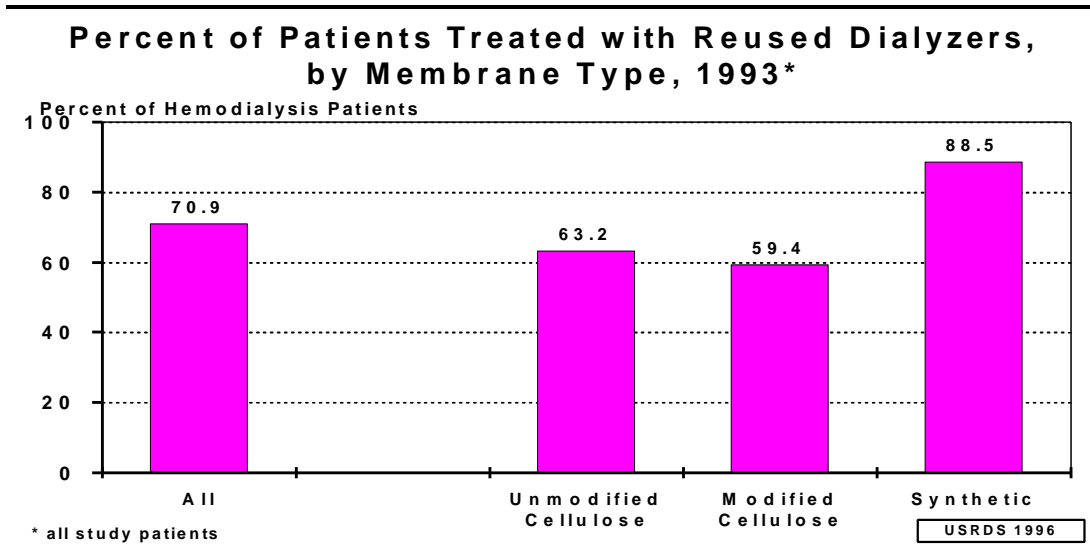


Figure IV - 10

Percent of patients treated with reprocessed hemodialyzers by dialyzer membrane category in December 1993. No patient exclusions.

Reuse of Dialyzers

Among all patients sampled in the DMMS (incident and prevalent), 70.9 percent of patients were usually treated with reused dialyzers in December 1993 (Figure IV-10). The percent of patients treated with reused dialyzers was 63.2, 59.4 and 88.5 percent among patients treated with unmodified cellulose, modified cellulose, and synthetic membranes, respectively. These differences in reuse by membrane type may be in part related to differences in the cost of

dialyzers, which tend to be higher for many synthetic membranes. The reduction in the percent of patients reusing dialyzers in the DMMS compared to the CMAS occurred among patients using all membrane types, however the largest reduction was among the patients using modified cellulose membranes, followed by the unmodified cellulose membrane group.

The DMMS-1 also evaluated the reasons for patients not reusing dialyzers (Figure IV-11). Of patients not treated with reused dialyzers (29 percent),

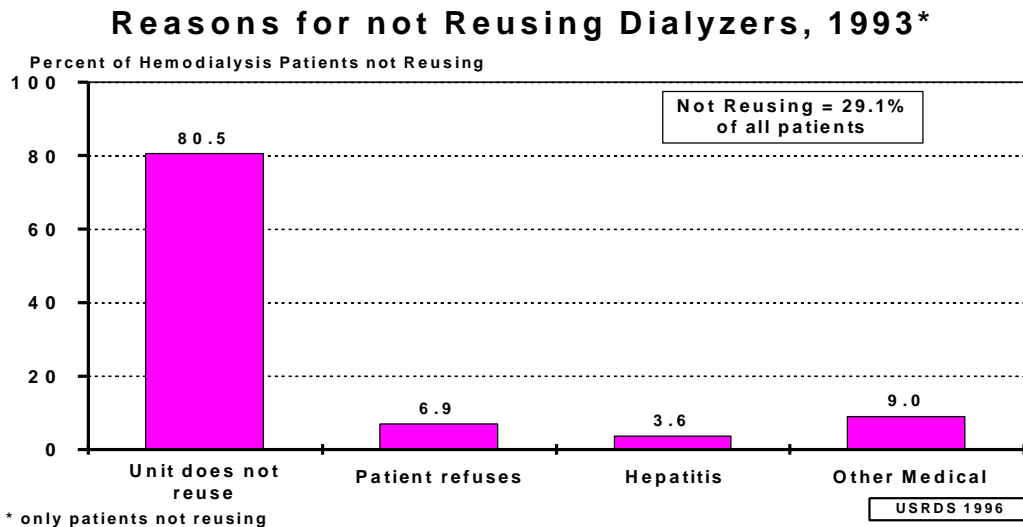


Figure IV - 11

Reasons for not using reprocessed dialyzers among the patients not reusing in December 1993 (i.e. 29.1 percent of all patients, no other exclusions).

Dialyzer Reuse Technique among U.S. Dialysis Facilities, 1995

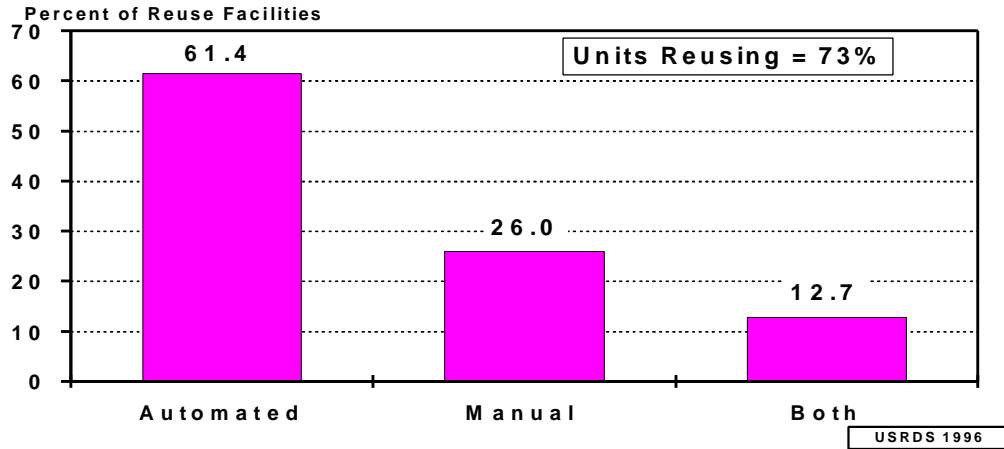


Figure IV - 12

Percent distribution of dialyzer reprocessing technique among facilities practicing reuse in December 1993 (i.e. 73 percent of all facilities).

approximately 80 percent were dialyzed in units that did not reuse, 7 percent refused reuse, 4 percent did not reuse for reason of hepatitis and 9 percent due to other medical conditions. Thus, 23.4 percent of patients were treated in non-reuse units and 70.9 percent were treated with reused dialyzers. The remaining 5.6 percent overall were not treated with reused dialyzers in reuse facilities because of medical reasons and patient refusal.

percent reported to be reusing dialyzers at the time of data abstraction in 1995. Of these, an automated sterilization technique was used in 61.4 percent, a manual technique was used in 26 percent and in 12.7 percent both automated and manual sterilization techniques were used (Figure IV-12).

Of all dialysis units sampled in this study, 73

The types of automated dialyzer reuse systems in U.S. facilities in December, 1993 were as follows: Renal Systems "Renatron™," (64 percent), Fresenius "DRS-4" (25.4 percent), NMC "semi-automated" (5.1 percent), Mesa Labs "Echo" (4.1 percent), and Other (1.5 percent).

Automated Dialyzer Reuse Systems used among U.S. Facilities, Dec 1993

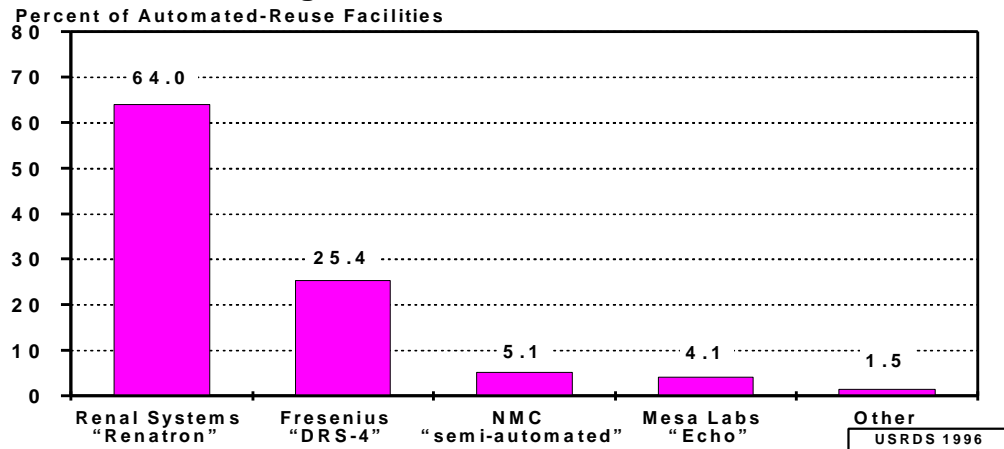


Figure IV - 13

Automated dialyzer reuse systems used among U.S. facilities, December 1993.

Dialyzer Germicide used for Reuse among U.S. Dialysis Facilities

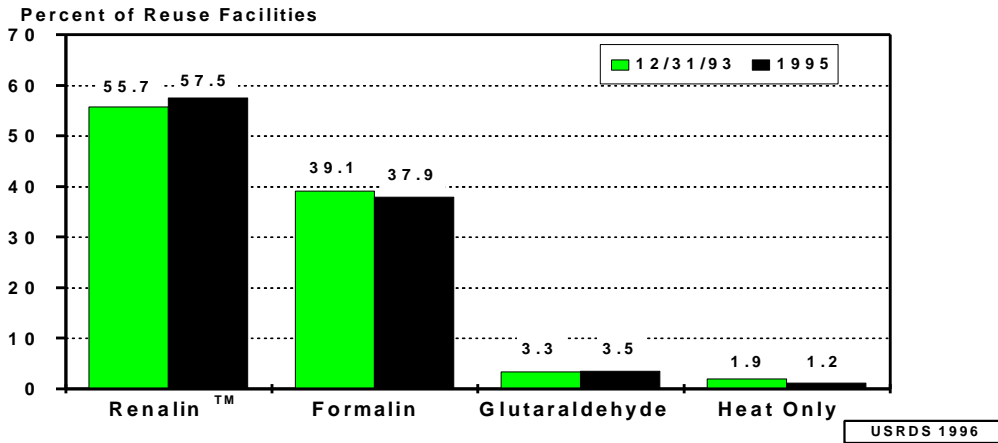


Figure IV - 14

Percent distribution of dialyzer germicides used for reprocessing among facilities practicing reuse in December 1993 and in the same facilities in 1995.

system (5.1 percent), Mesa Labs “Echo” (4.1 percent) and other (1.5 percent) as shown in Figure IV-13.

The dialyzer germicide used for reuse among the dialysis facilities sampled, both at the end of December 1993 and at the time of data abstraction (1995) are shown in Figure IV-14. In 1995, 57.5 percent of patients were using peracetic acid / acetic acid / peroxide mixture (Renalin™), a slight increase in percent compared to the end of 1993; 37.9 percent were using formaldehyde (Formalin), a slight decrease

in percent compared to the end of 1993; 3.5 percent were using glutaraldehyde and 1.2 percent were using heat alone.

Figure IV-15 shows that the percent of dialysis units that also use bleach for sterilization varied by dialyzer germicide. Seventy percent of facilities using formaldehyde (Formalin), 57 percent of units using Glutaraldehyde, and 3 percent of units using peracetic acid mixture (Renalin™) were also using bleach in 1995.

Use of Bleach by Dialyzer Germicide Among U.S. Dialysis Facilities, Dec 1993

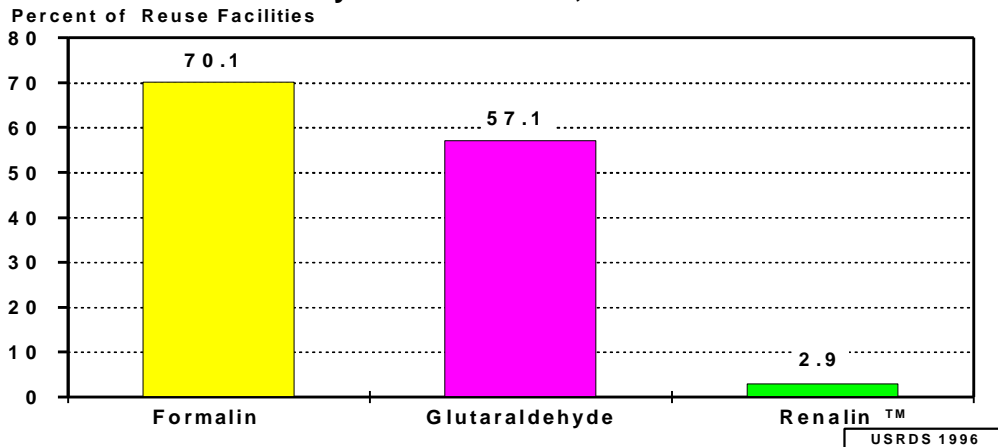


Figure IV -15

Use of bleach among facilities practicing reuse by germicide in December 1993.

Type of Water Treatment used for Reprocessing Dialyzers* and for Dialysate, U.S. Dialysis Facilities 1995 (1)

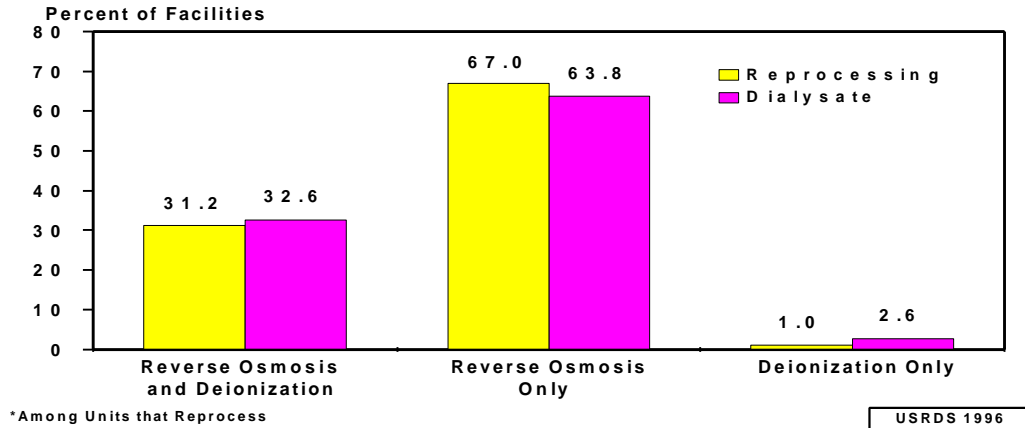


Figure IV - 16

Percent of facilities using reverse osmosis and/or deionization for reprocessing of dialyzers (among reuse facilities only) and for dialysate preparation (among all study facilities) in 1995.

The dialysis facility questionnaire also obtained data regarding the reuse of blood tubing. Among dialysis facilities that reused dialyzers, 12.4 percent reported that blood tubing was also reused.

Water Treatment

Among the dialysis facilities sampled, 100 percent used a public water system rather than a well source. Almost all dialysis facilities that were reusing

dialyzers reported use of a water softener (94.2 percent) and use of activated charcoal filtration (88.2 percent) for water used to reprocess dialyzers. Similarly, for water used for preparation of dialysate, among all units (reusing and non-reusing) a water softener was used in 91.2 percent and activated charcoal was used in 86.3 percent. In addition to these water treatments, almost all units used one of the following: 1) reverse osmosis alone, 2) reverse

Type of Water Treatment used for Reprocessing Dialyzers* and for Dialysate, U.S. Dialysis Facilities 1995 (2)

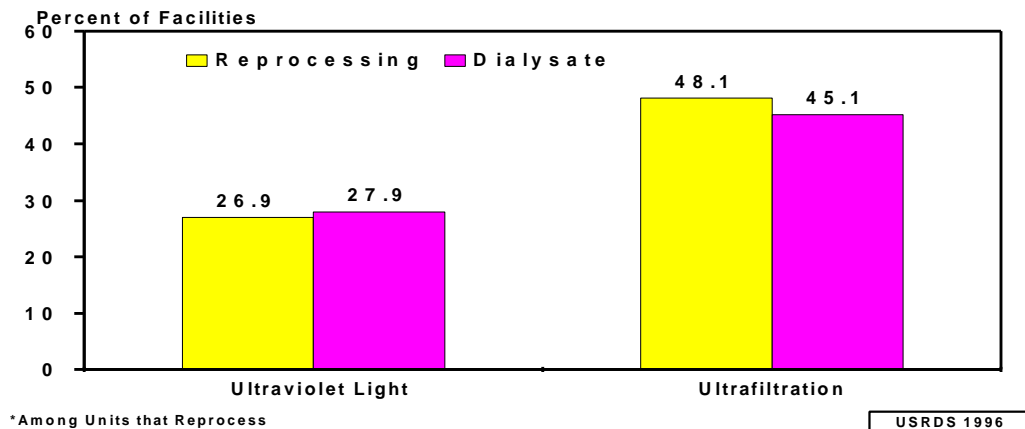


Figure IV - 17

Percent of facilities using ultraviolet light or ultrafiltration as additional water treatment for dialyzer reprocessing (among reuse facilities only) and for dialysate preparation (among all study facilities) in 1995. (Facilities may use both).

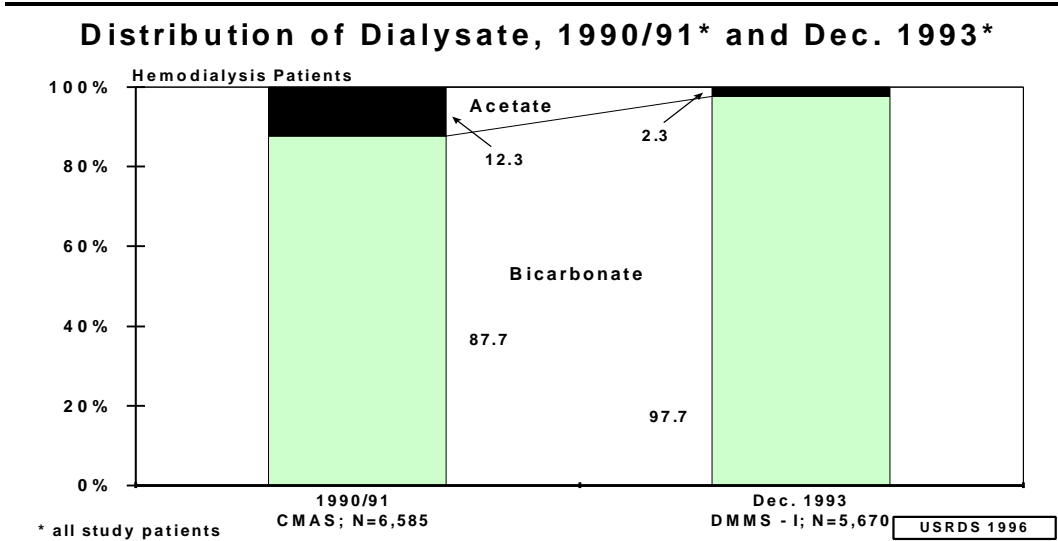


Figure IV - 18

Distribution of patients using bicarbonate versus acetate in dialysate in 1990/91 (CMAS) and December 1993 (DMMS Wave 1). No patient exclusions.

osmosis together with deionization or 3) deionization alone. Reverse osmosis alone was used in 67 and 63.8 percent, reverse osmosis and deionization was used in 31.2 and 32.6 percent, and deionization alone was used in 1 and 2.6 percent for water used to reprocess dialyzers (among reusing facilities) and for dialysate (among all facilities), respectively (Figure IV -16). Additionally, ultraviolet light treatment was used in 26.9 and 27.9 percent and ultrafiltration was used in 48.1 and 45.1 percent (not mutually exclusive) for

reprocessing of dialyzers (reusing facilities only) and for dialysate preparation (all facilities), respectively (Fig IV-17).

Dialysate

There has been a trend of greater use of bicarbonate dialysate for chronic hemodialysis which began in the late 1970's/early 80's after the description of "acetate intolerance" and technical advances which allowed the use of bicarbonate as a

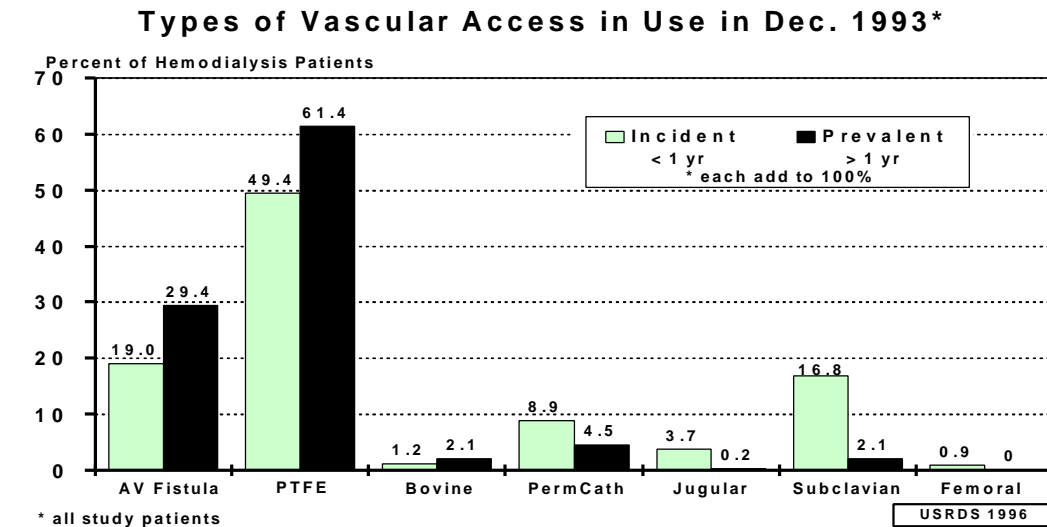


Figure IV - 19

Distribution of incident (< 1 year ESRD) versus prevalent (> 1 year ESRD) patients by vascular access type in use in December 1993. No patient exclusions.

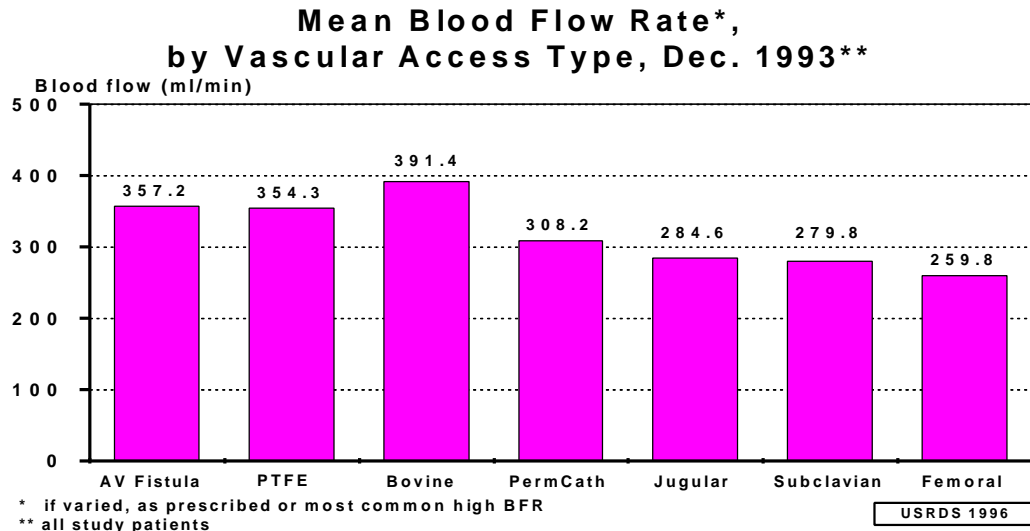


Figure IV -20

Mean blood flow rate by vascular access type in use in December 1993. When blood flow varied either the prescribed or the most common "high" rate was recorded. No patient exclusions.

base. The DMMS data show a further reduction in the use of acetate dialysate for hemodialysis on a national level with only 2.3 percent of all patients sampled using this type of dialysate (Figure IV-18). This compares to approximately 12 percent of patients using acetate in the U.S. in 1990/91 according to data from the CMAS.

access was obtained among patients who started dialysis in 1993 (incident patients), data for Figure IV-19 and IV-20 were obtained on all patients sampled as part of the DMMS "core" component. Figure IV-19 shows the type of vascular access in use in December 1993 for ESRD patients treated less than one year and greater than one year.

Vascular Access

Although the majority of data regarding vascular

PTFE grafts were used over 2 times more commonly than AV fistulas among both incident and prevalent patients. Among incident patients,

Distribution of Vascular Access Types in Use, at One Month After Start of HD, 1993*

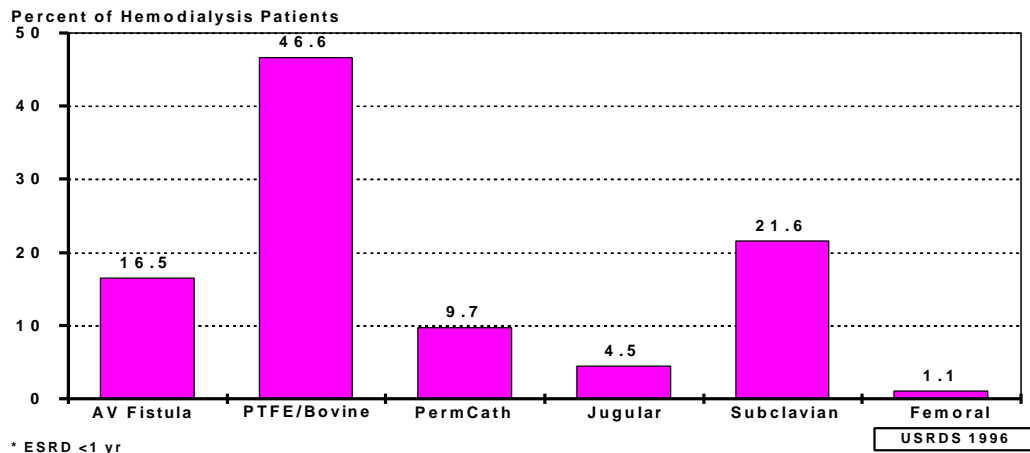


Figure IV -21

Distribution of patients with long-term vascular access type at access placement (for all access types) by time since multiple incident ESRD (long-term patients starting dialysis) in 1993.

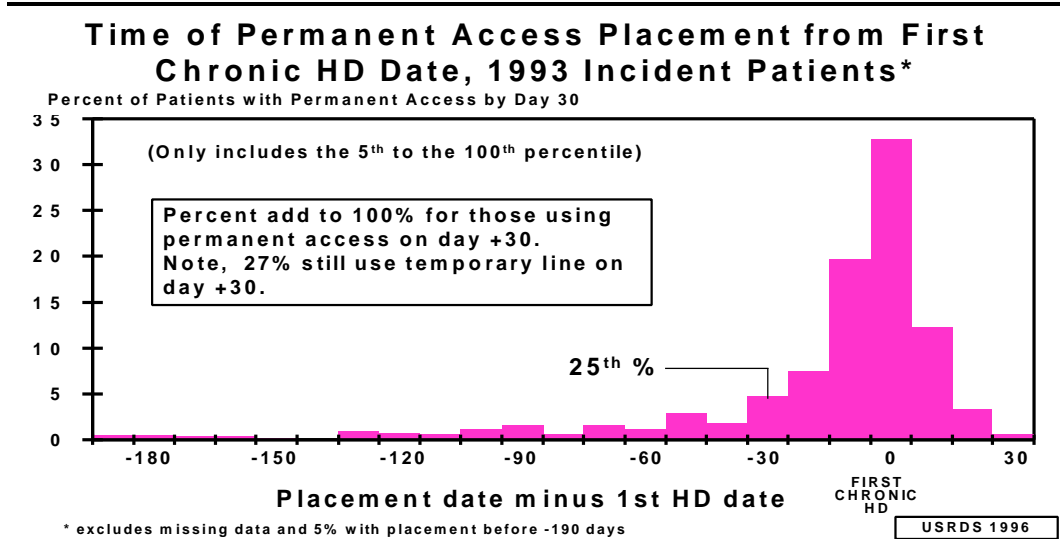


Figure IV -22

Distribution of time of placement of permanent access from first chronic hemodialysis date among patients who had a permanent access on day 30 of ESRD. Includes incident patients (<1 year ESRD).

approximately 70 percent were using either an AV fistula or PTFE/bovine graft, 8.9 were using a permanent indwelling catheter (e.g. Perm cath), and over 20 percent were using a temporary catheter. The subclavian vein was by far the most common access site for a temporary catheter, in comparison to the internal jugular or femoral vein. Compared to incident patients, prevalent patients were more likely to be using an AV fistula or PTFE/Bovine graft (93 percent), and were less likely to be using a permanent catheter (4.5 percent) or temporary catheter (2.3 percent).

Figure IV-20 shows the mean blood flow by vascular access type. Blood flows are highest for permanent arterio-venous access types (AV fistula, PTFE, Bovine), intermediate for permanent catheters and lowest for temporary catheters. This figure suggests that among patients with temporary catheters, those with femoral catheters have the lowest blood flows (however as depicted in Figure IV-19, this estimate is based on a relatively small number of patients). The following data regarding vascular access pertain to patients on dialysis for less than one year (incident only).

Figure IV-21 indicates that in only 43.9 percent of patients was a permanent access placed or attempted before the onset of ESRD. Figure IV-22 shows the distribution of time to placement of a permanent access among patients who had a permanent access in

use on day 30 of ESRD. It is striking to note that only 25 percent of patients had a permanent access placed more than one month prior to onset of ESRD therapy, even though it is preferred that access placement occurs before this time.

Figure IV-23 shows the distribution of vascular access types in actual use at one month after the initiation of chronic hemodialysis. It is similar to Figure IV-19 in format with the exception that PTFE and Bovine grafts (a small percentage) are combined. At one month, dialysis treatments were performed using a functioning fistula in only 16.5 percent and using a PTFE/Bovine graft in only 46.6 percent. Combined, only 63 percent of new patients had a functioning permanent AV access (fistula or graft) at one month after hemodialysis initiation. At this time, 27 percent of patients were using a temporary catheter and 9.7 percent were using a permanent catheter.

Despite concerns of the development of subclavian vein stenosis, the subclavian vein was used as the access site at one month for 79 percent of patients with a temporary access, followed by the internal jugular (17 percent) and femoral veins (4 percent). Comparing Figure IV- 23 with Figure IV-19, it appears that as time on dialysis increases (incident = 0-12 months and prevalent = greater than 1 year), the utilization of permanent AV access types increases and the use of temporary and permanent catheters decreases.

At one month, the dialysis access in use is less likely to be an AV fistula in diabetics compared to nondiabetics (13.6 percent vs. 19.4 percent) and more likely to be a PTFE/bovine graft (49.3 percent vs. 43.8 percent). Diabetics and nondiabetics are equally likely to be using a permanent (9-10 percent) or temporary catheter (27 percent). Likewise, females are less than half as likely to be using an AV fistula than males (10.4 percent vs. 22.4 percent) and more likely to be using a graft (53.0 percent vs. 40.3 percent) or a permanent catheter (10.6 percent vs. 8.9 percent). Patients age 65 or over were less likely to be using a AV fistula (13.8 percent vs. 19.2 percent) and were more likely to be using a graft (49.5 percent vs. 44 percent) than patients less than 65 years.

Figure IV-24 shows the type of revision for the first revision or procedure to the access in use at one month. Surgical declotting was reported to be the most common procedure performed (42.3 percent), followed by medical declotting (14.8 percent), surgical revision (12.8 percent), creation of a new PTFE graft (10.7 percent), angioplasty with thrombolysis (8.1 percent), and angioplasty without thrombolysis (3.4 percent), creation of a new AV fistula (1.3 percent) and other procedures (6.7 percent).

Treatment of Anemia

Type of First Revision/Procedure for Permanent Access in Use at One Month, 1993-95*

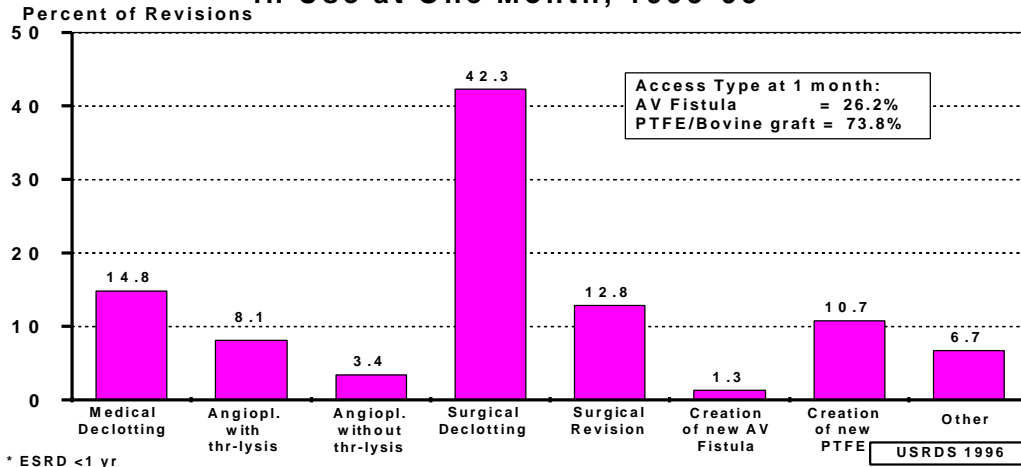


Figure IV - 24

Type of first revision/procedure among patients requiring a revision/procedure to their permanent access in use at one month during 1993-95. Includes incident patients (ESRD < 1 year). Permanent access includes AV fistula, PTFE graft, and Bovine graft

Distribution of Hematocrit, 1993*

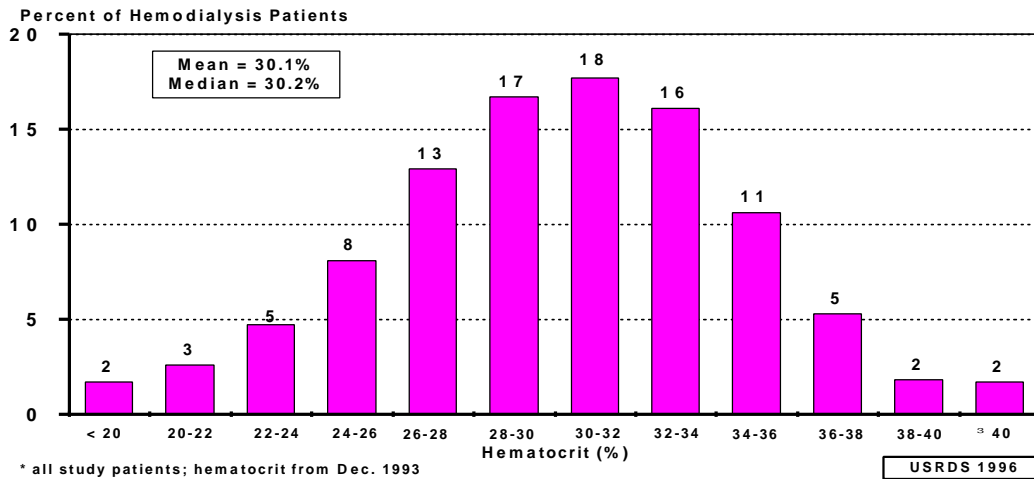


Figure IV -25

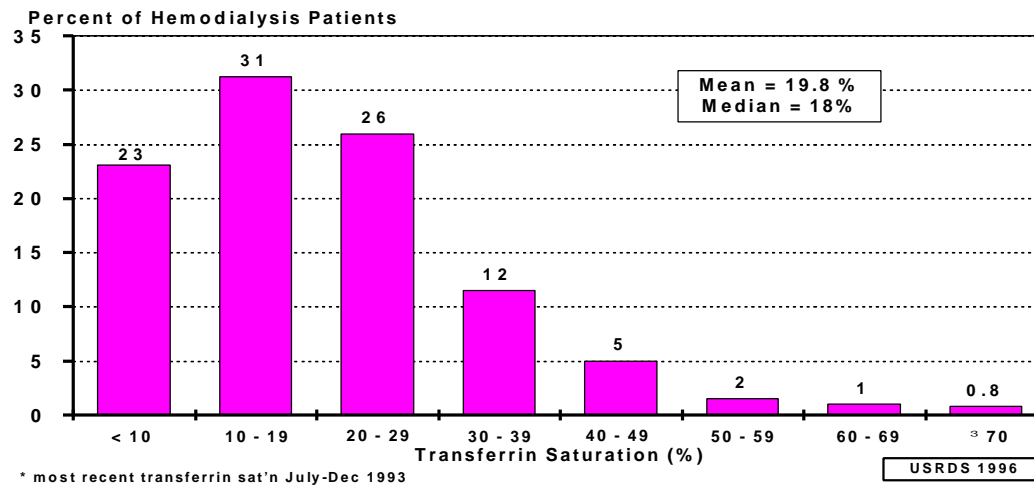
Distribution of hemodialysis patients receiving EPO by age and sex, in 1993. DMMS-1 includes all patients with a hematocrit reading from an EPO study.

The wide-spread use of recombinant human erythropoietin has resulted in substantial changes in the treatment of anemia among dialysis patients. The percent of hemodialysis patients on EPO by age and sex is shown in Figure IV -25 for the randomly selected sub-sample of patients in the DMMS-1 anemia study (N=2613). In all subgroups, over 80 percent of patients are using this therapy.

Males appear to receive EPO less frequently than females, particularly in the youngest adult age category. Among males, EPO utilization increases by age whereas among females, it is highest in both the youngest and oldest age categories. There has been a remarkable reduction in the fraction of hemodialysis patients receiving transfusions since the introduction of EPO, and an increase in hematocrit by year (since

Hematocrit* Before EPO Start Date

Distribution of Transferrin Saturation, 1993*



A comparison of hematocrit readings from Figure EPO-28. Patients who have both a hematocrit reading before the EPO start date and on the day of abstraction are patients with transferrin saturation, 1993 including EPO patients in DMMS-1. Hematocrit readings are most recent transferrin saturation readings are most recent EPO on the day of abstraction.

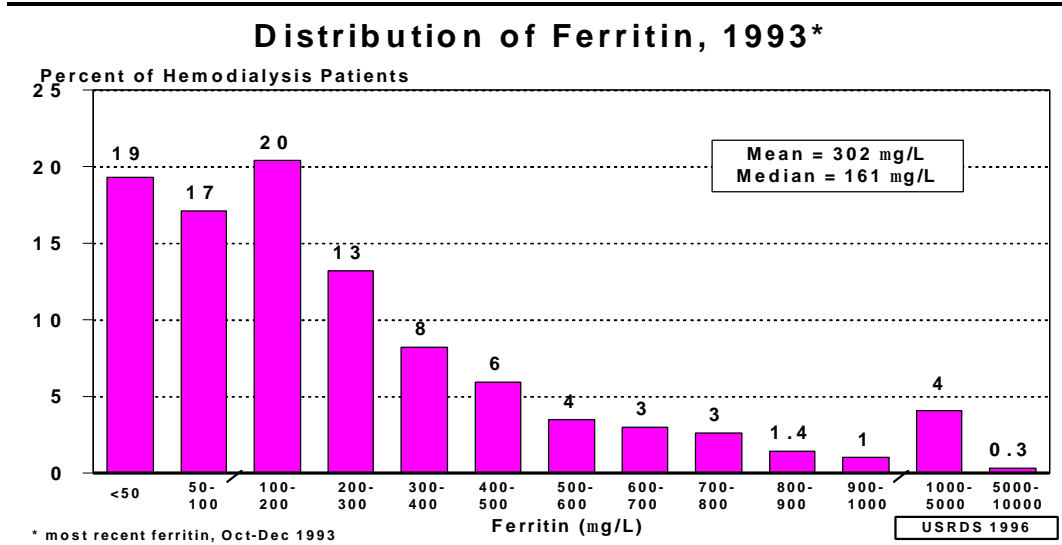


Figure IV -29

Distribution of patients by ferritin, 1993. Includes all patients in DMMS Wave 1 Anemia special study. Ferritin readings are most recent from Oct - Dec 1993.

1989) and by dose of EPO (USRDS 1995; see also Chapter III).

By nature of its design, the DMMS-1 has included a randomly selected cohort of hemodialysis patients treated with EPO. Among these patients, hematocrit increased from a mean of 26.2 percent before EPO to 29.8 percent at the time of data abstraction in 1995 as shown in Figure IV-26.

The mean hematocrit at abstraction among EPO treated patients for whom no pre-EPO hematocrit was available was very similar (30.2 percent). The mean hematocrit at the time of data abstraction among patients not treated with EPO was 32.2 percent.

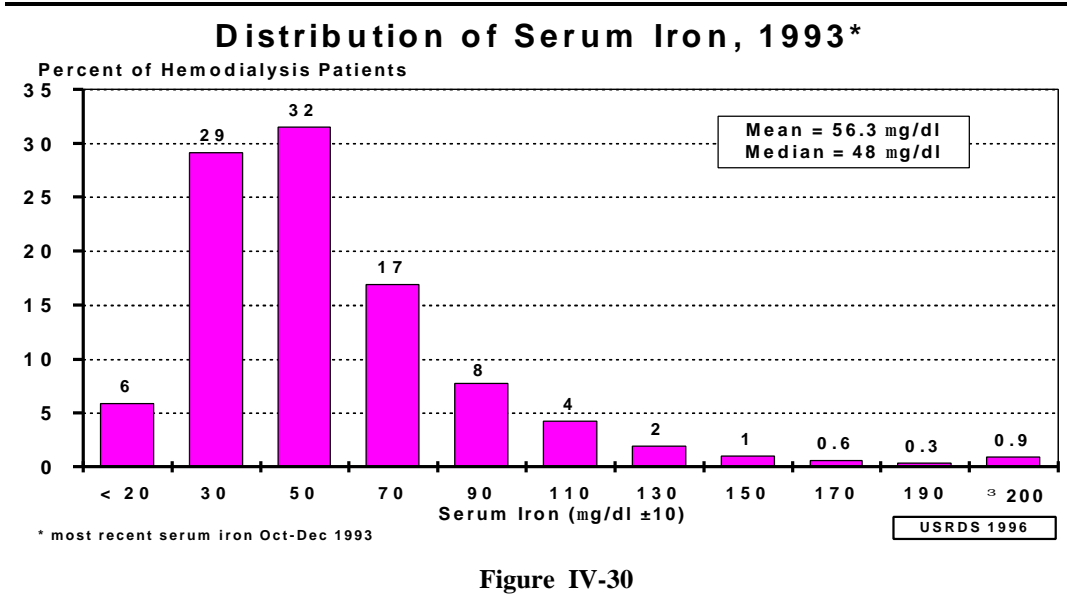
Figure IV - 27 shows the distribution of hematocrit for the DMMS sample of patients. Hematocrit appears to be normally distributed around a mean of 30.5 percent. Forty-eight percent of patients have a hematocrit between 30 and 36 percent, which is the suggested target range. Nine percent of patients were reported to have values above 36 percent. However, it should be noted that despite the wide-spread use of EPO seen in Figure IV - 25, 43 percent of hemodialysis patients continued to have a hematocrit of less than 30 percent.

Several factors are known to influence the magnitude of rise in hematocrit associated with EPO treatment, including availability of iron stores, dose of

EPO, aluminum toxicity, infection, blood loss, dose of dialysis and elevated parathyroid hormone levels. Resistance to EPO therapy may occur if the patient is iron deficient. DMMS-1 evaluated the frequency of iron deficiency by several parameters, since there is no single best indicator of iron availability. Iron saturation greater than 20 percent with ferritin levels greater than 100-200 are generally recommended for patients treated with EPO. The distribution of transferrin saturation (i.e. serum iron/total iron binding capacity) for all patients sampled in this study (both EPO treated and untreated) is shown in Figure IV - 28.

Over 50 percent of patients had a transferrin saturation less than 20 percent and over two thirds of these had values of less than 10 percent. The mean value was 19.8 percent. The distribution of serum ferritin, shown in Figure IV - 29 shows that approximately 56 percent of patients had a serum ferritin of less than 200 µg/L, 36 percent had a level less than 100 µg/L and 19 percent had a level less than 50 µg/L.

The distribution of serum iron, which is a less useful measure of iron availability, revealed that 35 percent of patients had values below 40 µg/dl and 32 percent had values of 40 to 60 µg/dl (Figure IV - 30).

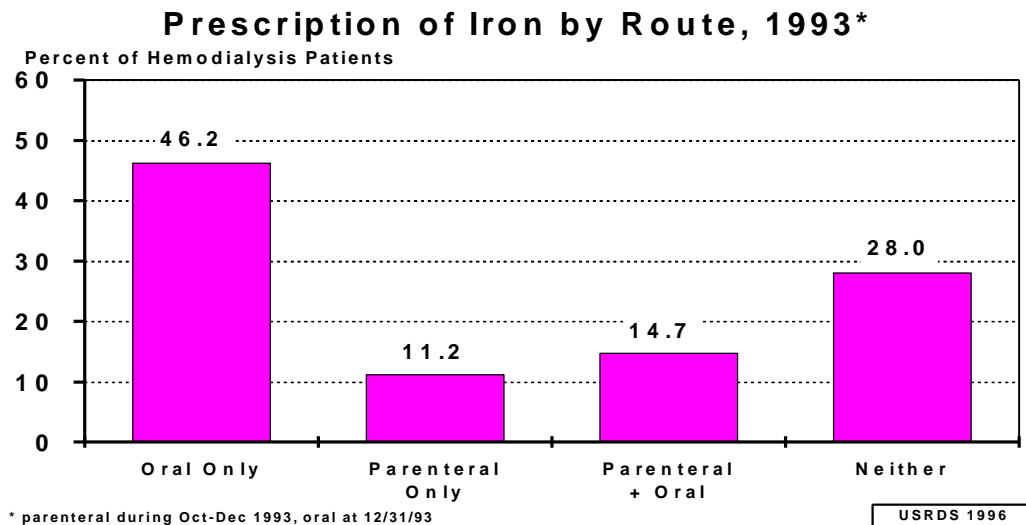


Distribution of patients by serum iron, 1993. Includes all patients in DMMS Wave 1 Anemia special study. Serum iron readings are most recent from Oct - Dec 1993.

These figures suggest that a substantial proportion of hemodialysis patients have indicators of iron deficiency at a time when parenteral iron was available (after a gap in 1991 and early 1992 --see Chapter III). Among all patients sampled (both EPO treated and untreated), 46.2 percent were reported to be taking oral iron in December 1993, 11.2 percent were reported to have used parenteral iron at some time during October to December 1993, additionally, 14.7

percent were using oral and had used parenteral during October to December 1993 and 28 percent had not used either oral or parenteral iron. (Figure IV-31). Of patients using parenteral iron, 99.7 percent did so by the intravenous route and the remainder were by intramuscular injection.

Among patients receiving EPO, 92.5 percent were receiving it intravenously and 7.5 percent, subcutaneously. Figure IV-32 shows the distribution of



Distribution of patients by iron use and route, 1993. Includes all patients in DMMS Wave 1 Anemia special study. Reported use of oral iron is for December 1993 and reported use of parenteral iron is for any time during Oct-Dec 1993.

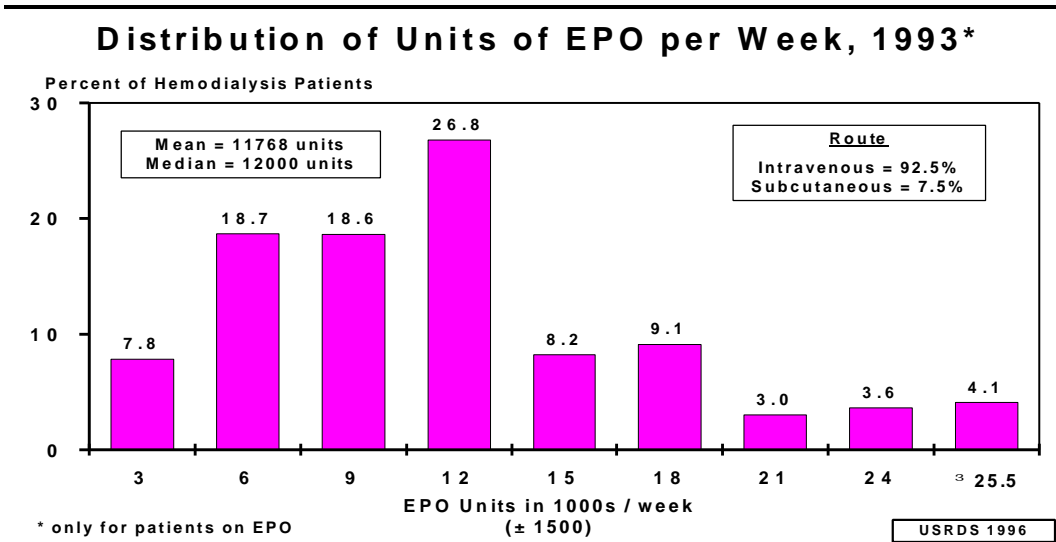


Figure IV-32

Distribution of patients by dose of EPO administered per week, December 1993. Includes all patients on EPO in DMMS Wave 1 Anemia special study.

units of EPO administered per week. Approximately 27 percent of patients received 12,000 +/- 1500 units per week (mostly 4000 units per dialysis session based on thrice weekly dialysis). Forty-five percent of patients received lower doses and 28 percent received higher doses. Over 4 percent of patients received more than 25,000 units per week. Approximately 87 percent of in center hemodialysis patients received it three times per week, 8 percent two times per week and 5 percent one time per week. The mean dose per administration was 4259 units.

Conclusions

The data from DMMS-1 presented in this chapter are useful in that they describe the actual practices regarding dialysis dose, dialysis membrane, reuse technique, water treatment, vascular access and treatment of anemia among hemodialysis patients in the United States.

Since these data are based on a random sample of hemodialysis patients, they can likely be generalized to the national experience. More detailed analyses are planned which will evaluate practices within specific subgroups, the possible associations of these treatment parameters with each other, and the relationships of these factors with a number of important outcomes.

References

Acchiardo SR, Runyan K, Hatten KW, Dyson B, Fuller J, Moore L: Impact of Kt/V and protein

catabolic rate on hemodialysis mortality. *J Am Soc Nephrol* 3: 351, 1992.

Collins A, Liao M, Umen A, Hanson G, Keshaviah P: Diabetic hemodialysis patients treated with a high Kt/V have a lower risk of death than standard Kt/V. *J Am Soc Nephrol* 2: 318, 1991.

Daugirdas JT: Second generation logarithmic estimates of single-pool variable volume of Kt/V: An analysis of error. *J Am Soc Nephrol* 1993; 4: 1205-1213.

Daugirdas JT. Chronic hemodialysis prescription. In: *Handbook of Dialysis*, Daugirdas JT, Ing TS (eds), Little, Brown and Company, Boston, 1994.

Daugirdas JT, Balter P, Burke MS, Priester-Coary A, Majka T: Screening for extreme postdialysis urea rebound using the Smye method. *J Am Soc Nephrol* 1995;6:596. National Institutes of Health: *Morbidity and Mortality in Dialysis*. NIH Consensus Statement 1993; 11(2): 1-33.

Hakim RM, Breyer J, Ismail N, Schulman G: Effects of dose of dialysis on morbidity and mortality. *Am J Kidney Dis* 23: 661-669, 1994.

Held PJ, Brunner F, Odaka M, Garcia JR, Port FK, Gaylin DS. Five-year survival for end-stage renal disease patients in the United States, Europe, and Japan, 1982-1987. *Am J Kidney Dis* 1990; 15: 451-457.

- Held PJ, Blagg CR, Liska DW, Port FK, Hakim R, Levin N. The dose of hemodialysis according to dialysis prescription in Europe and the United States. *Kidney Int* 1992; 42(suppl 38): S16-S21.
- Held PJ, Carroll CE, Liska DW, Turenne MA, Port FK. Hemodialysis therapy in the United States: What is the dose and does it matter? *Am J Kidney Dis* 1994; 24: 974-980.
- Held PJ, Port FK, Wolfe RA, Stannard DC, Daugirdas JT, Bloembergen WE, Greer JW, Hakim RM: The dose of hemodialysis and patient mortality. *J Am Soc Nephrol* 1996 (in press).
- Kopple JD, Hakim RM, Held PJ, Keane WF, King K, Lazarus JM, Parker TF, Teeham BP. Recommendations for Reducing the Higher Morbidity and Mortality of United States Maintenance Dialysis patients. *Am J Kidney Dis* 1994; 24: 968-973.
- Owen WF, Lew NL, Liu Y, Lowrie EG, Lazarus JM: The urea reduction ratio and serum albumin concentration as predictors of mortality in patients undergoing hemodialysis. *N Engl J Med* 1993; 329: 1001-1006.
- Petronis KR, Carroll CE, Held PJ, Port FK: Effect of race on access to recombinant human erythropoietin in long-term hemodialysis patients. *JAMA* 1994; 271: 1760-1763.
- Schleifer CR, Snyder S, Jones K: The influence of urea kinetic modeling on gross mortality in hemodialysis. *J Am Soc Nephrol* 2: 349, 1991.
- United States Renal Data System. USRDS 1995 Annual Data Report. National Institutes of Health, National Institutes of Diabetes and Digestive and Kidney Diseases. Bethesda, MD, 1995.

