

1999 ANNUAL REPORT ESRD CLINICAL PERFORMANCE MEASURES PROJECT (Formerly ESRD Core Indicators Project)

OPPORTUNITIES
TO IMPROVE CARE FOR
ADULT IN-CENTER HEMODIALYSIS and
ADULT PERITONEAL DIALYSIS PATIENTS

DECEMBER 1999



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Data on in-center hemodialysis patients are from October–December 1998

Data on peritoneal dialysis patients are from October 1998–March 1999

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I. BACKGROUND

The Social Security Amendments of 1972 (PL 92-603) extended Medicare coverage to individuals with end-stage renal disease (ESRD) or chronic kidney failure who require dialysis or a kidney transplant to maintain life. To qualify for Medicare under the renal provision, a person must have ESRD and either be entitled to a monthly insurance benefit under Title II of the Social Security Act (or an annuity under the Railroad Retirement Act); or be fully or currently insured under Social Security; or be the spouse or dependent child of a person who meets at least one of these last two requirements. There is no minimum age for eligibility under the renal disease provision. The incidence of treated ESRD in the United States is 180 per million population and continues to rise at a rate of 7.8% per year. (1) As of December 31, 1998, there were 245,710 patients receiving dialysis therapy in the United States. (2)

The Health Care Financing Administration (HCFA), which oversees the Medicare program, contracts with 18 ESRD Network Organizations throughout the United States. The ESRD Networks perform oversight activities to assure the appropriateness of services and protection for ESRD patients. In 1994, HCFA, with input from the renal community, reshaped the approach of the ESRD Network program to quality assurance and improvement in order to respond to the need to improve the care of Medicare ESRD patients. (3) This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP gives the ESRD Networks and HCFA a chance to demonstrate that health care provided to renal Medicare beneficiaries can be measurably improved. The HCQIP is based on the assumption that most health care providers need and welcome both information and, where necessary, help in applying the tools and techniques of quality management. (4)

One activity included in the ESRD HCQIP was the National/Network ESRD Core Indicators Project (CIP). The ESRD CIP was HCFA's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD. (5) This project established the first consistent clinical ESRD database. The elements included in the database represent clinical measures thought to be indicative of key components of care surrounding dialysis. As such, the data points are considered "indicators" for use in triggering improvement activities.

Section 4558(b) of the Balanced Budget Act (BBA) of 1997 requires HCFA to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, HCFA funded the development of Clinical Performance Measures (CPMs) based on the National Kidney Foundation's (NKF) Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines. (6, 7, 8, 9) On April 1, 1998, HCFA awarded a contract to PRO-West, a private, non-profit health care quality improvement organization with headquarters in Seattle, to develop a set of ESRD CPMs based on the NKF DOQI Guidelines.

To accomplish this work, PRO-West established four workgroups composed of individuals from the renal community (Appendix 1) to assist in the development of the CPMs. Sixteen ESRD CPMs (five for hemodialysis adequacy, three for peritoneal dialysis adequacy, four for vascular access, and four for anemia management) were developed and delivered to HCFA on December 1, 1998. Appendix 2 lists the descriptions of these 16 CPMs.

These initial CPMs were developed to assist dialysis facility staff, ESRD Networks, dialysis patients, and other stakeholders in conducting quality improvement initiatives and activities.

On March 1, 1999, the ESRD Core Indicators Project was merged with the ESRD CPM Project and this project is now known as the ESRD CPM Project. The ESRD CPMs are similar to the core indicators with the addition of measures for assessing vascular access. During the summer of 1999, the collection of clinical data to calculate these measures was pilot tested on a national random sample of adult in-center hemodialysis patients, stratified by Network area, and a national random sample of adult peritoneal dialysis patients.

This 1999 Annual ESRD CPM Project Report provides the results of some of these CPMs on a sample of adult in-center hemodialysis patients and adult peritoneal dialysis patients; it does not provide results on a dialysis facility-specific basis. The quality of dialysis services is reported for adult in-center hemodialysis patients for the last quarter in 1998 and adult peritoneal dialysis patients for the time period October 1998–March 1999.

HCFA and the ESRD Networks are committed to improving ESRD patient care and outcomes by providing tools that can be used by the renal community

in assessing patient care processes and outcomes and identifying opportunities for improvement. One of these tools includes data feedback reports based on the clinical information obtained from the ESRD CPM Project, formerly known as ESRD CIP. We invite the renal community to provide us with ideas and feedback as to ways HCFA and the Networks can best help the community improve patient care.

II. PROJECT METHODS

The purpose of the ESRD CPM Project is to provide comparative data to ESRD caregivers to assist them in assessing and improving the care provided to ESRD patients. From 1994 to 1998, HCFA collected ESRD data under the ESRD CIP. The data collected in 1994 (for the time period October–December 1993) established a baseline estimate for important clinical measures of care for adult in-center hemodialysis patients in the United States. (10) These data were again collected in 1995, for the October–December 1994 time period. In addition, data for peritoneal dialysis patients were collected for the November–December 1994 and January–April 1995 time periods. (11, 12)

The third data collection effort for the ESRD CIP was conducted in 1996 (13) to determine whether patterns in these clinical measures had changed and if opportunities to improve care continued to exist. To identify further opportunities to improve care, the fourth data collection effort, conducted in 1997, examined data from October–December 1996 for in-center hemodialysis patients and from November–December 1996 and January–April 1997 for peritoneal dialysis patients. (14)

The fifth and final ESRD CIP data collection effort was conducted in 1998 to identify further opportunities to improve care. Data were examined from October–December 1997 for in-center hemodialysis patients, and from November–December 1997 and January–April 1998 for peritoneal dialysis patients. (15)

The first data collection effort for the ESRD CPMs (which is the subject of this report) was conducted in 1999 and examined data from October–December 1998 for in-center hemodialysis patients, and from October–December 1998 and January–March 1999 for peritoneal dialysis patients. The primary purposes of this collection effort were to pilot test the CPMs developed in Phase I of the project and to identify further opportunities to improve care.

The Sample

Annually, each ESRD Network conducts a survey of ESRD facilities to validate the census of ESRD patients in the Network at the end of the calendar year. In March 1999, a listing of adult (aged ≥ 18 years as of September 30, 1998) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 1998, was obtained from each of the 18 ESRD Networks. The listing included, but was not limited to, the following information about each patient who met the project criteria: last name, first name, middle initial, date of birth, gender, race, Social Security and/or Health Insurance Claim number, underlying etiology of ESRD, date that dialysis was initiated, and provider number of the facility where the patient was dialyzing.

From this universe of patients, a national random sample, stratified by Network, of in-center hemodialysis patients was drawn. The sample size of in-center hemodialysis patients was selected to allow estimation of a proportion with a 95% confidence interval around that estimate no larger than 10 percentage points (i.e., $\pm 5\%$) for Network-specific estimates of the key Hemodialysis CPMs and ESRD CIP measures. Additionally a 30% over-sample was drawn to compensate for an anticipated non-response rate and to assure a large enough sample of the in-center hemodialysis patient population who were dialyzing at least six months prior to October 1, 1998. The final sample consisted of 8,838 in-center hemodialysis patients.

The peritoneal dialysis patient sample was a national random sample. The sample size was selected to allow estimation of a proportion with a 95% confidence interval around that estimate no larger than 10 percentage points (i.e., $\pm 5\%$) within each of the three age groups (aged 18 to 44 years; aged 45 to 64 years; aged 65 or more years) for national (not Network-specific) estimates of the key Peritoneal CPMs and ESRD CIP measures. Additionally, a 10% over-sample was drawn to compensate for an anticipated non-response rate. The final sample consisted of 1,650 peritoneal dialysis patients.

Finally, a 5% national random sample of hemodialysis facilities was also drawn and consisted of 179 hemodialysis facilities.

Data Collection

Three data collection forms were used: a four-page in-center hemodialysis form, a six-page peritoneal

dialysis form, and a one-page hemodialysis facility-specific form (Appendices 3, 4, 5); the use of these forms was authorized through the National Institutes of Health (NIH) clinical exemption process. Descriptive information on each selected patient and hemodialysis facility was printed onto gummed labels, which were placed on the appropriate data collection forms before the forms were sent to individual ESRD Networks and facilities for completion. If demographic information (e.g., name, date of birth, race) or clinical information (e.g., date that initial dialysis occurred) was incorrect, facility staff were asked to correct the information on the forms. Staff at ESRD facilities were also asked to abstract ethnicity and clinical information from the medical record of each selected patient.

In April 1999, the data collection forms for patients and facilities in the sample were distributed to ESRD facilities. Completed forms were returned to the appropriate Network, where data were reviewed for acceptability and manually entered into an Epi Info, v.6.04a file. (16) In August 1999, each Network sent a copy of the resulting Epi Info, v.6.04a, file to PRO-West in Seattle, where the data were aggregated and then submitted to HCFA for the initial analysis.

Clinical information contained in the medical record was abstracted for each patient in the hemodialysis sample who received in-center hemodialysis during October, November, and December 1998. Clinical information contained in the medical record was also abstracted for each patient in the peritoneal dialysis sample who was receiving peritoneal dialysis during the two-month periods of October–November 1998, December 1998–January 1999, and February–March 1999. The abstraction forms used for data collection are included in Appendices 3, 4, and 5.

Clinical Performance Measures (CPMs) and Core Indicators

The clinical information abstracted by facility staff is used in this report to describe some of the 16 CPMs that were developed from the NKF DOQI Guidelines and the core indicators for several conditions of care for adult dialysis patients. The CPMs were developed in the areas of hemodialysis and peritoneal dialysis adequacy, vascular access and anemia management. A complete description of the 16 CPMs appears in Appendix 2. The CPMs used for this report were modified slightly from previous versions for clarification and to facilitate data analysis.

The Hemodialysis Adequacy CPMs described in this report are:

- I. The patient's delivered dose of hemodialysis is measured at least once per month.
- II. The patient's delivered dose of hemodialysis reported in the patient's chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula for Kt/V, or by using urea reduction ratio (URR).
- III. The patient's delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month study period) of hemodialysis is either $Kt/V \geq 1.2$ or $URR \geq 65\%$.

The Peritoneal Dialysis Adequacy CPMs described in this report are:

- I. The patient's total solute clearance for urea and creatinine is measured routinely (defined for this report as at least once during the six-month study period).
- II. The patient's total solute clearance for urea (weekly Kt/V_{urea}) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 2.)
- III. For patients on continuous ambulatory peritoneal dialysis (CAPD), the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.0 and a weekly creatinine clearance of at least 60 L/week/1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For cycler patients without a daytime dwell, the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.2 and a weekly creatinine clearance of at least 66 L/week/1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For cycler patients with a daytime dwell, the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.1 and a weekly creatinine clearance of at least 63 L/week/1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

The clinical information collected to calculate these adequacy CPMs also allows us to describe other aspects of dialysis adequacy (or core indicators), such as the mean Kt/V and URR values for hemodialysis patients in each Network area and in the US.

The Vascular Access CPMs described in this report are:

- I. A primary arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of all prevalent patients undergoing hemodialysis.
- II. Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for > 90 days) as their permanent chronic dialysis access.
- IV. A patient's AV graft should be routinely monitored for stenosis. (See Vascular Access CPM IV in Appendix 2 for a list of techniques and frequency of monitoring used to screen for the presence of stenosis.)

The Anemia Management CPMs described in this report are:

- I. The target hemoglobin is 11-12 gm/dL and the target hematocrit is 33-36%.
- II.
 - a. For anemic patients (hemoglobin < 11 gm/dL, or hematocrit < 33%) or patients prescribed Epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) at least once in a three-month period.
 - b. For all anemic patients (hemoglobin < 11 gm/dL, or hematocrit < 33%) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation $\geq 20\%$ were documented during the three-month study period.
- III. All anemic patients (hemoglobin < 11 gm/dL, or hematocrit < 33%) or patients prescribed Epoetin, and with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was $\geq 50\%$ or the mean serum ferritin concentration was ≥ 800 ng/ml; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

The clinical information collected to calculate these

CPMs also allows us to describe other aspects of anemia management (or core indicators) such as mean hemoglobin values of 11–12 gm/dL for adult hemodialysis patients nationally and in each Network area and nationally for peritoneal dialysis patients, and the percent of patients with mean hemoglobin < 9 gm/dL (defined as severe anemia for this report).

All monthly recorded data were used in determining the percent of patients prescribed Epoetin, and the average weekly Epoetin dose was stratified by hemoglobin levels.

Serum Albumin

Although serum albumin is not a CPM for this data collection period, it is one of the original core indicators and was chosen as an indicator for assessing mortality risk for adult in-center hemodialysis patients and adult peritoneal dialysis patients. In this report serum albumin values are described separately for those patients whose blood was tested by the bromocresol green (BCG) method or by the bromocresol purple (BCP) method. These two methods are commonly used for determining serum albumin concentrations and have been reported to yield systematically different results—the BCG method yielding higher serum albumin concentrations than the BCP method. (17)

Mean serum albumin values < 3.5 gm/dL by the BCG method were defined as an indicator of inadequate serum albumin. Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we also defined a BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. Mean serum albumin values ≥ 4.0 gm/dL (BCG method) and ≥ 3.7 gm/dL (BCP method) were defined as an indicator of optimal serum albumin. Findings from this project allow us to describe the mean serum albumin value for hemodialysis patients in each Network area and nationally, and nationally for peritoneal dialysis patients.

III. INITIAL ANALYSIS

In-Center Hemodialysis

Initial analysis for the CPMs and core indicators focused on the following elements: paired pre-and post-dialysis BUN values (used to calculate URR values); paired pre-and post-dialysis BUN values with patient height and weight and dialysis session length (used to calculate Kt/V values); hemoglobin and hematocrit values; vascular access information; and serum albumin.

Inclusion of a case in the analysis required that data be available for at least one of the months in the three-month project period, with at least one paired pre- and post-dialysis BUN, at least one hemoglobin or one hematocrit, and at least one serum albumin. We were able to include for analysis 8,336 of the 8,838 patients from the sample (response rate = 94%). (TABLE 1)

Characteristics regarding the gender, race/ethnicity, age, and diagnosis of ESRD for these patients are shown in Table 2. As expected, the characteristics of this random sample were very similar to the characteristics of the overall US hemodialysis population. (18) Data regarding Epoetin use, serum ferritin concentrations, transferrin saturation levels, iron use, KUF (a measure of dialyzer clearance), and actual time on dialysis were also analyzed. The initial analysis utilized Epi Info and Statistical Package for the Social Sciences (SPSS) software. (16,19)

For this report, each patient's mean value for the three-month project period was determined from the available data for the following items: Kt/V, URR, time on dialysis, KUF, hemoglobin, hematocrit, and serum albumin. Because we had data from a stratified random sample of patients (i.e., a separate random sample from each of the 18 Network areas), it was necessary to weight the collected data in order to obtain unbiased estimates of mean clinical values for the total population. This weighting was done according to the proportion of each Network's total population sampled. Aggregate national results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

Peritoneal Dialysis

Initial analysis focused on the adequacy of dialysis CPMs, anemia management CPMs, and serum albumin values. Inclusion of a case for analysis required that the patient received peritoneal dialysis at least one month during the time period October 1998–March 1999. Of the 1,650 patients sampled, 1,533 patients were included for analysis (93% response rate). (TABLE 3) Selected patient characteristics of this sample for analysis are shown in Table 4.

For this report, each patient's mean value for the six-month study period was determined from available data for the following items: weekly Kt/V_{urea}, weekly creatinine clearance, hemoglobin, hematocrit, serum albumin, Epoetin dosing, serum ferritin concentrations, and transferrin saturation levels. Iron use for the patients in this sample was analyzed. The data are from a random

sample, not stratified by Network; thus, only national aggregate data are reported. No Network-specific analyses were conducted.

Report Format

This report describes the clinical performance measures and core indicators findings for both the in-center hemodialysis patient sample and the peritoneal dialysis patient sample in separate sections—VI and VII, respectively—for the following study period: October–December 1998 for the in-center hemodialysis patients, and October 1998–March 1999 for the peritoneal dialysis patients.

The national results are presented separately in tables by gender, race/ethnicity, age groups (18-44, 45-64, and 65+ years of age), and diagnosis of ESRD. The diagnoses are categorized as diabetes mellitus (DM), hypertension (HTN), glomerulonephritis (GN), and other/unknown. In some instances clinical characteristics for patients in each Network area are also shown. Selected results are highlighted in figures.

In addition, key findings from the 1999 CPM study (describing patterns of clinical measures from October–December 1998 for in-center hemodialysis patients and October 1998–March 1999 for peritoneal dialysis patients) are compared to key findings from previous study periods.

Note Regarding Race:

In this report several tables describe important clinical characteristics of adult in-center hemodialysis and peritoneal dialysis patients for the following race groups: American Indian/Alaska Native, Asian/Pacific Islander, African-American, Caucasian, and other/unknown. In the figures, these clinical characteristics are compared by race group; however, the comparisons are limited to Caucasian vs. African-American. The reason for this is sample size. Because of small sample size (Table 2), the 95% confidence intervals (see note regarding statistics) for estimates for Asian/Pacific Islander, American Indian/Alaska Native, or other/unknown race groups are very broad. On the other hand, the sample size for Caucasian and African-American patients was large enough to provide stable estimates; i.e., the 95% confidence intervals are narrow.

Note Regarding Statistics:

Readers may be interested to know if some of the patterns of clinical characteristics in this report show a statistically significant difference; e.g., comparisons among age groups, racial groups, or geographic areas. To assist readers, we have included 95% confidence interval (CI) brackets (I) on selected bar charts. If the upper limit of one group's bracket does not overlap with the lower limit of another group's bracket, then the difference between the two groups is statistically significant. In Figure 9, for example, the percent of all women receiving adequate dialysis is statistically significantly higher than the percent of all men receiving adequate dialysis.

TABLE 1: Number of adult (aged ≥ 18 years) in-center hemodialysis patients in each Network in December 1998, sample size and response rate for the 1999 ESRD CPM Project.

Network	#HD Patients Dec 1998	Sample Size	# Acceptable Forms [^]	Response Rate %
1	8,181	485	443	91.3
2	16,701	497	466	93.8
3	9,509	489	466	95.3
4	11,170	492	447	90.8
5	13,982	494	464	93.9
6	19,544	498	482	96.8
7	12,333	493	455	92.3
8	14,163	495	472	95.4
9	13,958	494	476	96.4
10	9,275	488	449	92.0
11	12,949	494	455	92.1
12	7,788	485	446	92.0
13	9,594	489	479	98.0
14	17,745	498	471	94.6
15	8,788	488	472	96.7
16	5,033	472	455	96.4
17	10,386	490	471	96.1
18	15,945	497	467	94.0
Total	217,044	8,838	8,336	94.3

[^] A form was considered acceptable if the patient met the selection criteria for inclusion in the study and if data were provided for at least one of the months in the fourth quarter of 1998 for the following items: 1) hematocrit or hemoglobin; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

Two or more monthly values for these clinical measures were available for 92% of patients for hemoglobin, 93% of patients for hematocrit, and 96% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 84% of patients; monthly hematocrit values were available for 86% of patients. At least one monthly paired pre-and post-dialysis BUN value was available for 100% of patients, and two or more were available for 94%. Monthly paired pre- and post-dialysis BUN values were available for 81% of patients.

TABLE 2: Characteristics of adult (aged ≥ 18 years) in-center hemodialysis patients in the 1999 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 1997.

Patient Characteristic	1999 CPM Sample for Analysis		All US in 1997*	
	# [^]	%	# in 1000s	%
TOTAL	8336	100	191.5	100
GENDER				
Men	4449	53	100.4	52
Women	3878	47	91.1	48
RACE/ETHNICITY				
American Indian/ Alaska Native	169	2	3.2	2
Asian/Pacific Islander	329	4	6.7	4
African-American	3145	38	75.0	39
Caucasian	4167	50	103.1	54
Other/Unknown	526	6	3.5	2
Hispanic	994	12		
AGE GROUP (years)				
18-44	1412	17	31.8**	17
45-64	3202	38	69.8	36
65+	3720	45	88.9	46
DIAGNOSIS				
Diabetes mellitus	3423	41	73.8	39
Hypertension	2127	26	55.1	29
Glomerulonephritis	1027	12	23.7	12
Other/Unknown	1759	21	38.9	20

*USRDS: 1999 Annual Data Report, Bethesda, MD, National Institutes of Health, 1999.

[^] Subgroup totals may not equal 8,336 due to missing data.

** For ages 20-44 years

Note: Percents may not add up to 100% due to rounding.

TABLE 3: Number of adult (aged ≥ 18 years) peritoneal dialysis patients in each Network's sample and response rate for the 1999 ESRD CPM Project.

Network	# Peritoneal Dialysis Patients in Dec. 1998	Sample Size	# Acceptable Forms [^]	Response Rate %
1	1317	74	62	83.8
2	1812	99	93	93.9
3	1395	77	71	92.2
4	1167	70	55	78.6
5	1533	88	86	97.7
6	2534	163	145	89.0
7	1210	71	69	97.2
8	1371	102	97	95.1
9	2312	126	115	91.3
10	1044	71	64	90.1
11	1980	115	108	93.9
12	1535	88	85	96.6
13	986	75	74	98.7
14	1620	98	91	92.9
15	1096	70	67	95.7
16	891	76	70	92.1
17	1421	70	68	97.1
18	1806	117	113	96.6
Total	27030	1650	1533	92.9

[^] A form was considered acceptable if the patient was receiving peritoneal dialysis at least once during the six-month study period and had met the selection criteria for inclusion in the study.

IV. IMPROVEMENTS AND OPPORTUNITIES TO IMPROVE CARE

By describing the prevalence of important clinical characteristics of adult in-center hemodialysis patients in the US for the last quarter of each year (October–December) 1993, 1994, 1995, 1996, 1997, and again in 1998, this project has documented important improvements in, and continuing opportunities to improve, care for these patients.

Striking improvement in the adequacy of dialysis for

TABLE 4: Characteristics of adult (aged ≥ 18 years) peritoneal dialysis patients in the 1999 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 1997.

Patient Characteristic	1999 CPM Sample for Analysis		All US in 1997*	
	# [^]	%	# in 1000s	%
TOTAL	1533	100	26.7	100
GENDER				
Men	760	50	13.6	51
Women	772	50	13.0	49
RACE/ETHNICITY				
American Indian/ Alaska Native	34	2	0.4	1.5
Asian/Pacific Islander	56	4	1.1	4
African-American	404	26	6.7	25
Caucasian	928	61	17.9	67
Other/Unknown	111	7	0.6	2
Hispanic	152	10		
AGE GROUP (years)				
18–44	402	26	6.9**	26
45–64	687	45	10.9	41
65+	444	29	8.1	30
DIAGNOSIS				
Diabetes mellitus	505	33	9.2	34
Hypertension	332	22	5.8	22
Glomerulonephritis	299	20	5.2	19
Other/Unknown	397	26	6.5	24

* USRDS: 1999 Annual Data Report, Bethesda, MD, National Institutes of Health, 1999.

[^] Subgroup totals may not equal 1,533 due to missing data.

** For ages 20–44 years

Note: Percents may not add up to 100% due to rounding.

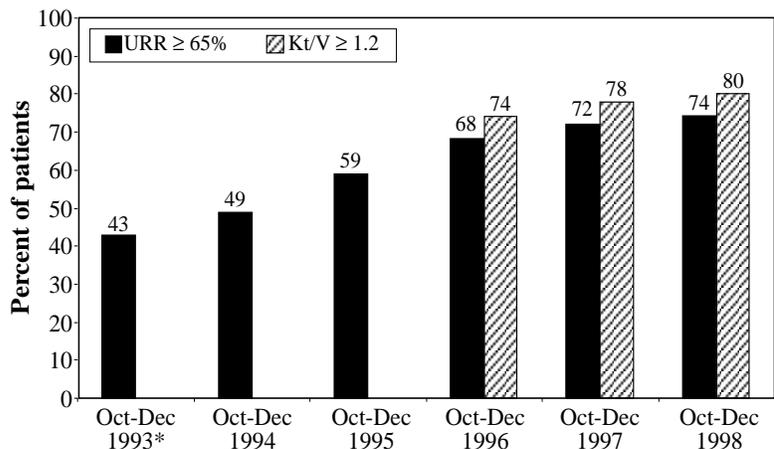
in-center hemodialysis patients occurred. However, important opportunities to improve this care remain.

In the last quarter of 1998, 80% of the sampled adult in-center hemodialysis patients in the US received dialysis that resulted in a delivered $Kt/V \geq 1.2$. The percent of patients receiving dialysis at this Kt/V level increased significantly, from 78% in late 1997 to 80% in late 1998. (FIGURE 2) This represents a significant improvement in care, with approximately 13,000 more in-center hemodialysis patients in the US receiving dialysis with $Kt/V \geq 1.2$ in late 1998 than would have been receiving dialysis at

this level in late 1996. (FIGURES 2, 3a)
 During October–December 1998, approximately 20% of the patients were receiving dialysis

with $Kt/V < 1.2$. A similar pattern was seen for the distribution of URR values over the six-year period from late 1993 to late 1998. (FIGURE 3b)

Figure 2: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean URR $\geq 65\%$ in October–December 1998 compared to October–December 1993*, 1994, 1995, 1996, and 1997, and percent of patients with mean $Kt/V \geq 1.2$, October–December 1998 compared to October–December 1996 and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 3a: Distribution of mean Kt/V values for adult (aged ≥ 18 years) in-center hemodialysis patients, October–December 1998 compared to October–December 1996 and 1997. 1999 ESRD CPM Project.

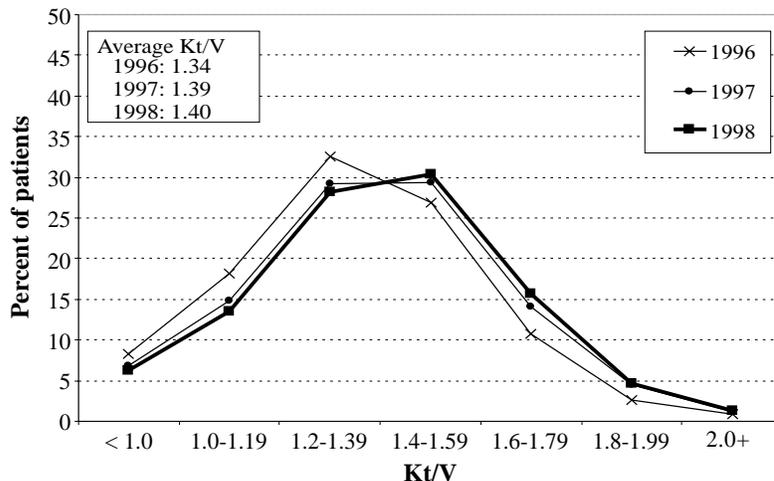
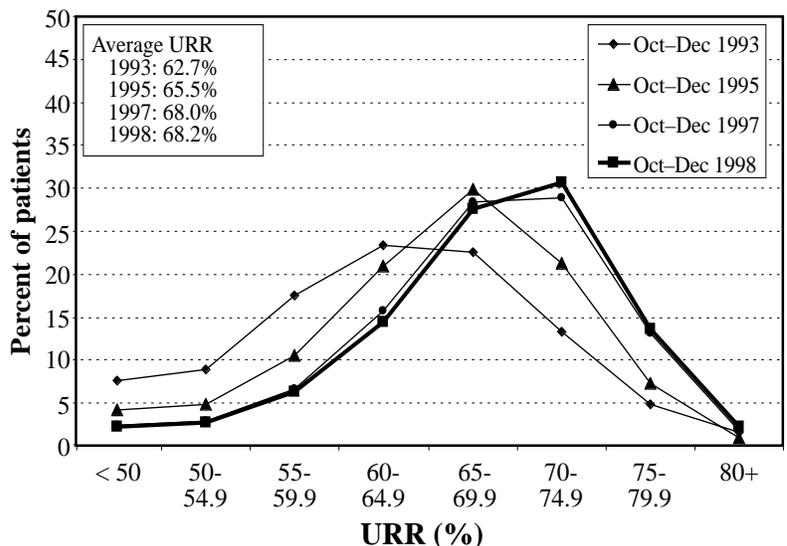


Figure 3b: Distribution of mean URR values for adult (aged ≥ 18 years) in-center hemodialysis patients, October–December 1998 compared to October–December 1993*, 1995, and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Another important improvement occurred in hemoglobin and hematocrit values of the sampled in-center hemodialysis patients. The percentage of patients with hemoglobin >10 gm/dL increased from 69% in late 1997 to 78% in late 1998. (FIGURES 4, 5a) In late 1993, 46% of adult in-center hemodialysis patients in the 16 participating Networks had a mean hematocrit > 30%; by late 1998 this percent had increased to 83% in all 18 Networks. (FIGURES 4, 5b) The goal of the National Anemia Cooperative Project is to raise the percentage of patients who have a hematocrit >30%. (20)

A similar improvement in hemoglobin values was seen in the sampled peritoneal dialysis patients, with 82% of patients having a mean hemoglobin > 10 gm/dL in the 1999 study period compared to 76% of patients in the 1998 study period. (FIGURE 6a) The average hematocrit for these patients was 32.5% in the 1995 study period, 33.1% in the 1996 study period, 33.8% in the 1997 and 1998 study periods, and 34.5% in the 1999 study period. (FIGURE 6b) The percentage of sampled peritoneal dialysis patients with a mean hematocrit > 30% was 64% in the 1995 study period, 70% in the 1996 study period, 76% in the 1997 study

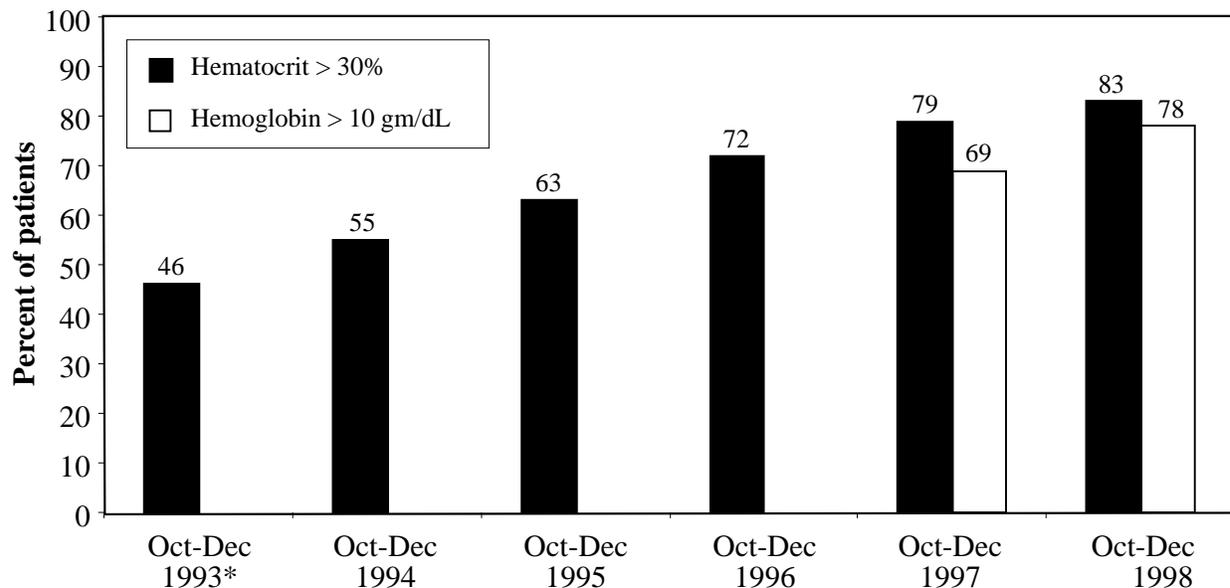
period, 78% in the 1998 study period, and 84% in the 1999 study period.

Improvement in the adequacy of dialysis occurred for CAPD patients. The mean weekly Kt/V_{urea} increased from 2.20 to 2.22, and the mean weekly creatinine clearance increased from 67.8 to 70.4 L/week/1.73 m² from study year 1998 to study year 1999. (FIGURES 7a, 7b)

The purpose of this report is to provide you with an initial look at the Network and national pictures of the clinical measures that were collected for the ESRD Clinical Performance Measures Project. The project was not designed to allow for facility-specific profiles of care.

As you review this information, ask yourself the following: What percentage of adult patients at your facility are receiving adequate dialysis ($Kt/V \geq 1.2$ or $URR \geq 65\%$ for in-center hemodialysis patients)? What percentage of your patients have an average hemoglobin > 10 gm/dL? How do these CPMs or indicators of care for your patients compare to the indicators described in this report? We want this report to stimulate you to answer questions such as these and, where indicated, to develop ways to improve care to your patients.

Figure 4: Percent of adult (aged ≥18 years) in-center hemodialysis patients with mean hematocrit > 30% in October–December 1998 compared to October–December 1993*, 1994, 1995, 1996, and 1997, and percent of patients with mean hemoglobin > 10 gm/dL, October–December 1998 compared to October–December 1997. 1999 ESRD CPM Project.



^Although many approximate the hematocrit by multiplying the hemoglobin by three (or dividing the hematocrit by three to approximate the hemoglobin), this formula is not a valid method to obtain the hematocrit or hemoglobin value because the relationship between hematocrit and hemoglobin differs significantly depending upon the instrumentation used to measure them. (21)

*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 5a: Distribution of mean hemoglobin values for adult (aged ≥18 years) in-center hemodialysis patients, October–December 1998 compared to October–December 1997. 1999 ESRD CPM Project.

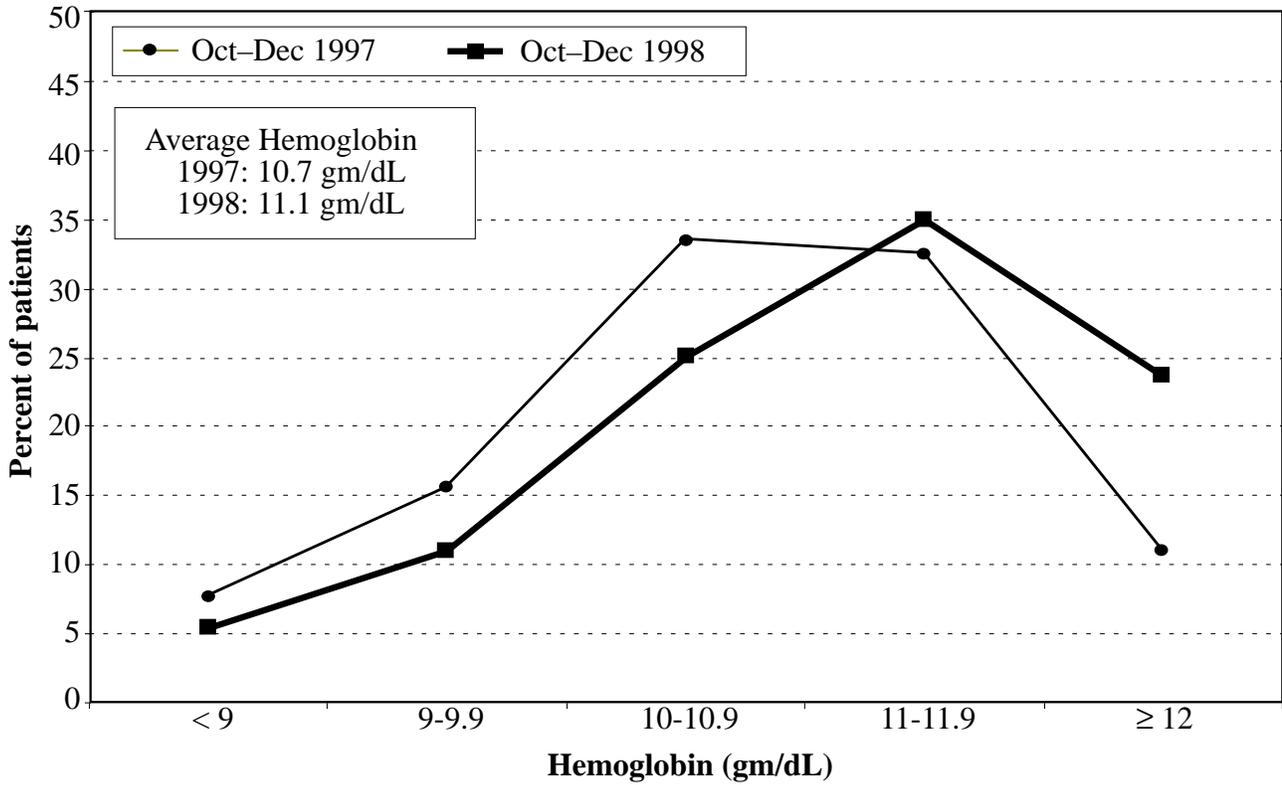
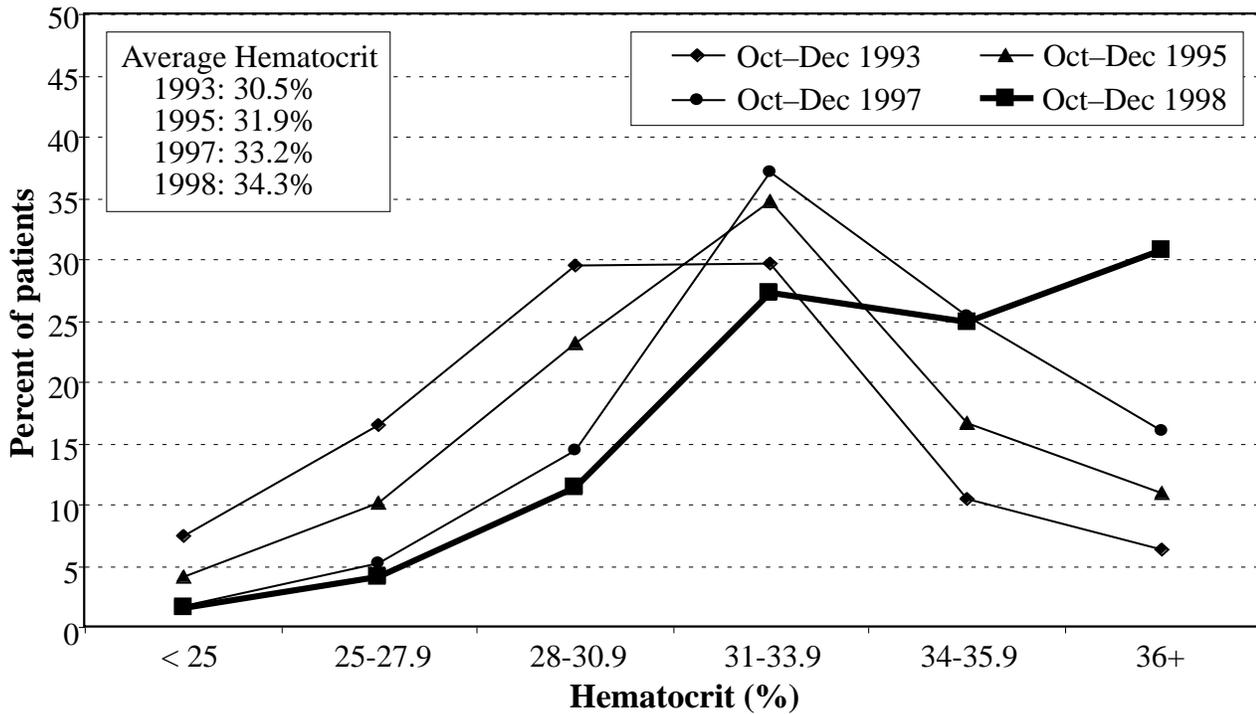


Figure 5b: Distribution of mean hematocrit values for adult (aged ≥18 years) in-center hemodialysis patients, October–December 1998 compared to October–December 1993*, 1995, and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 6a. Distribution of mean hemoglobin values for adult (aged ≥ 18 years) peritoneal dialysis patients, October 1998–March 1999 compared to November 1997–April 1998. 1999 ESRD CPM Project.

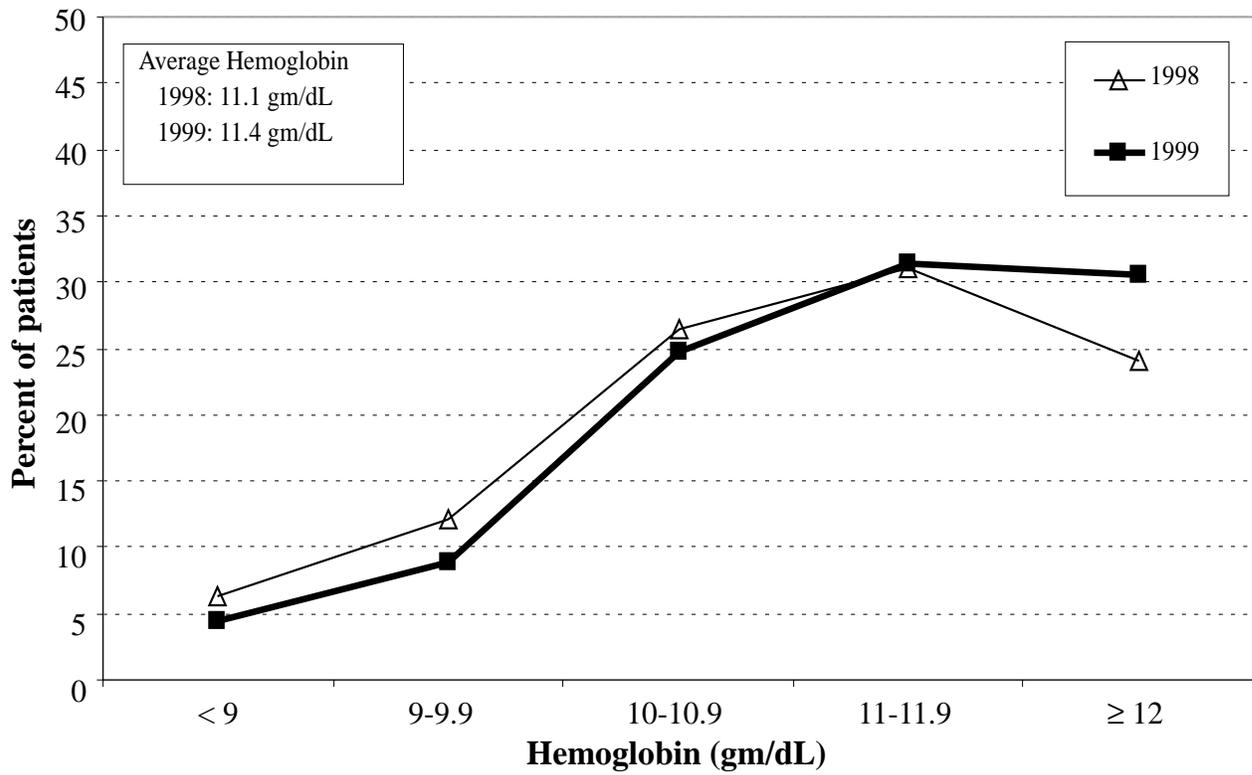


Figure 6b. Distribution of mean hematocrit values for adult (aged ≥ 18 years) peritoneal dialysis patients, October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.

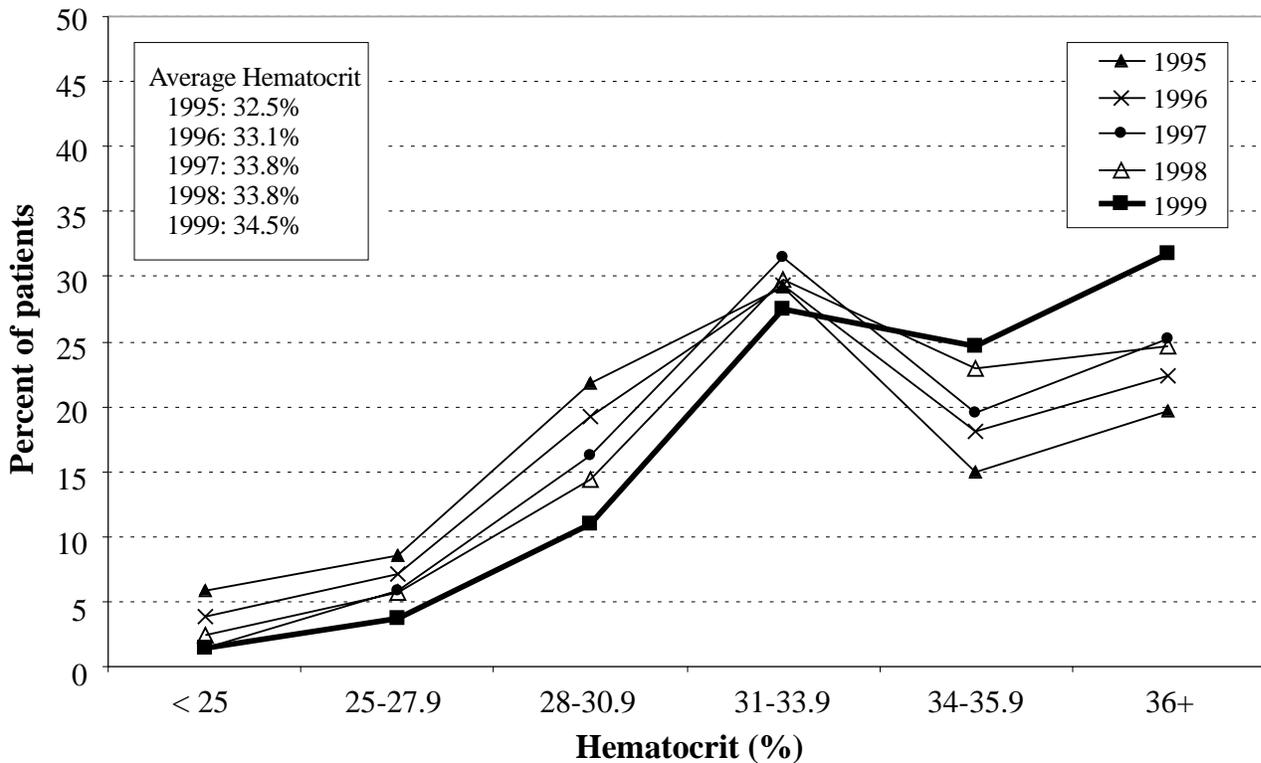


Figure 7a: Distribution of mean weekly Kt/V_{urea} values for adult (aged ≥ 18 years) CAPD patients, October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.

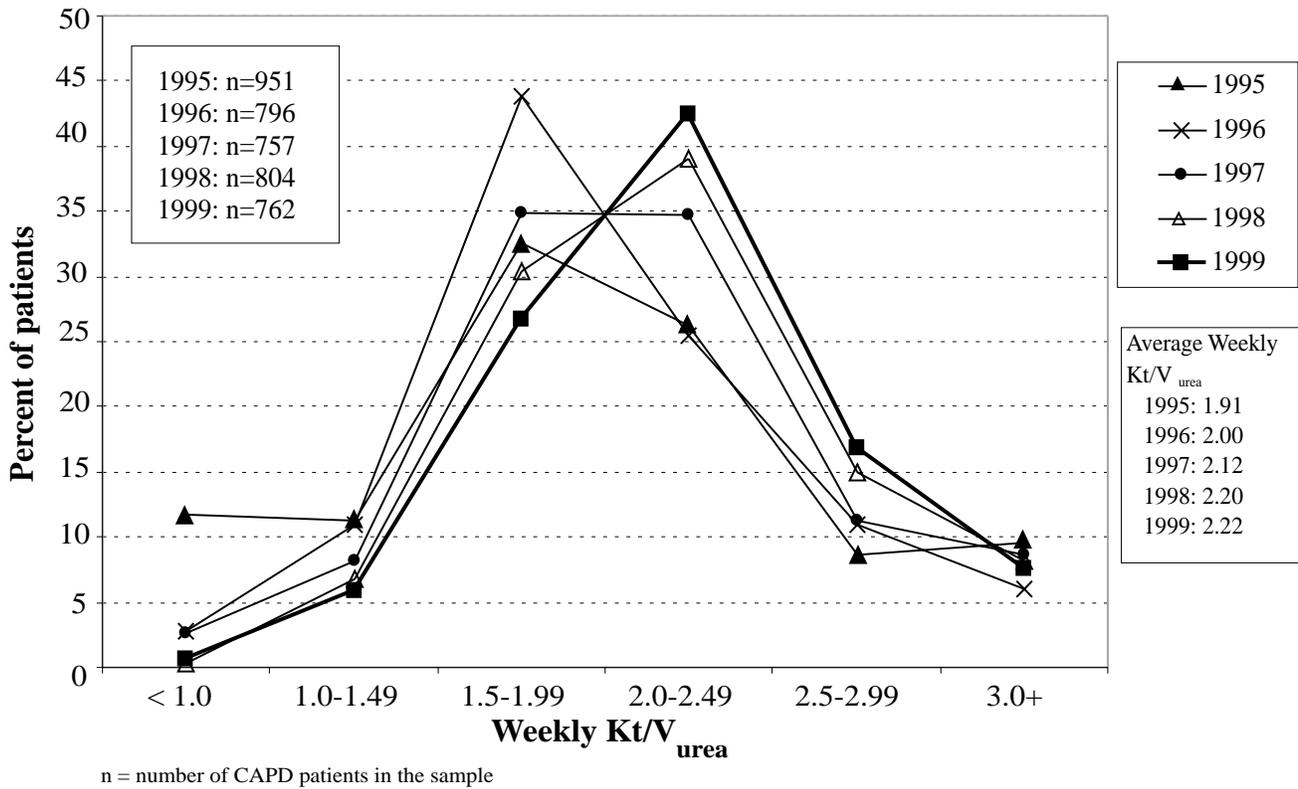
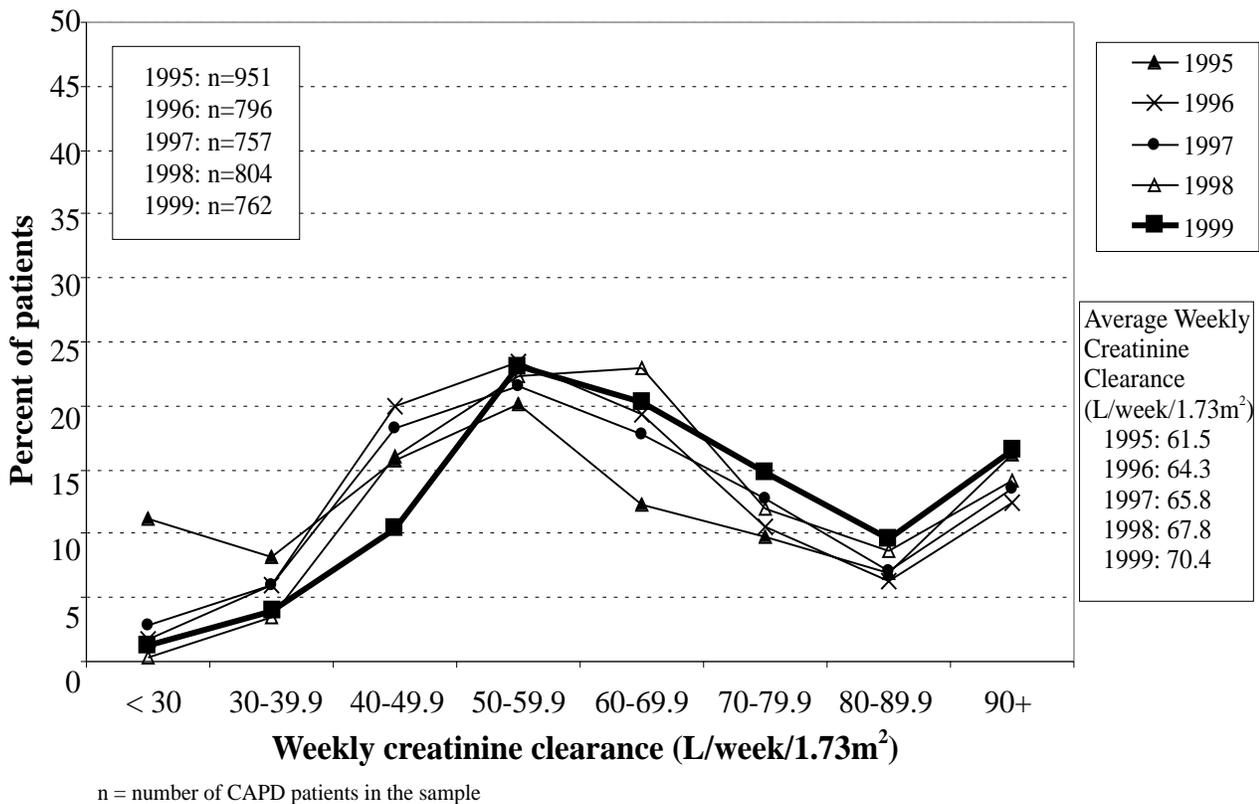


Figure 7b: Distribution of mean weekly creatinine clearance values (L/week/1.73m²) for adult (aged ≥ 18 years) CAPD patients, October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.



V. NEXT STEPS

Copies of the initial results of the 1999 ESRD CPM Project will be distributed to all dialysis facilities for the purpose of stimulating facility efforts to improve care. Your Network staff and Medical Review Board will be available to assist you in identifying and developing improvement efforts.

As mentioned previously, while significant improvements have occurred, the opportunity to improve care for adult in-center hemodialysis patients and adult peritoneal dialysis patients in the US in the area of adequacy of dialysis continues to be striking. Every ESRD facility should be familiar with the clinical practice guidelines on adequacy of dialysis developed by the Renal Physicians Association (22) and the NKF's DOQI. (6, 7) Factors that contribute to the inadequate delivery of dialysis are discussed in these documents.

Efforts to improve the adequacy of dialysis should be attentive to these factors.

In subsequent months, your ESRD Network will distribute to you additional data feedback reports. You may also find these reports on the Internet at www.hcfa.gov/quality/3h.htm. Please take the time to review these reports as you receive them and provide us with feedback as to the usefulness of the reports and ways you would like to see the clinical data displayed.

In the future, the ESRD Networks, in collaboration with ESRD facilities, will continue to assess the implementation of the ESRD CPMs in adult in-center hemodialysis patients and adult peritoneal dialysis patients in the US. The purpose of this effort will be to assess the improvement in care to these patients and encourage further improvements. The ultimate goal for this project is to improve care for these patients.

VI. IN-CENTER HEMODIALYSIS PATIENTS

A. SYNOPSIS

- Purpose of Project: The ultimate purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in improving the care provided to ESRD patients. The specific purposes of the 1999 project were:

To compare the prevalence of important clinical measures and/or characteristics of adult (aged ≥ 18 years) in-center hemodialysis patients in the US in October–December 1998 to the prevalence of those characteristics in the last quarter of each year (October–December) 1993, 1994, 1996, and 1997; AND, to identify opportunities to improve care for those patients.

- Method Used: A random sample of adult in-center hemodialysis patients who were alive on December 31, 1998, was selected (sample size 8,838).

ESRD facilities, with assistance from ESRD Networks, submitted to PRO-West clinical information about these patients for the time period October, November, December 1998 for aggregation. This aggregated data file was then forwarded to HCFA for initial analysis.

- Initial Findings: The sample for analysis consisted of 8,336 patients which was 94% of the original sample. Highlights from the initial findings are summarized below.

IMPROVEMENT OCCURRED

- 80% of the sampled patients were receiving dialysis with a delivered $Kt/V \geq 1.2$; from late 1997 to late 1998, there was a two percentage point increase in patients receiving dialysis with a delivered $Kt/V \geq 1.2$. (FIGURE 2)

- Seventy-eight percent of African-Americans and 81% of Caucasians were receiving dialysis with a mean delivered $Kt/V \geq 1.2$ in October–December 1998; from late 1997 to late 1998, this was a one percentage point increase for African-American patients and a three percentage point increase for Caucasian patients. (FIGURE 13a)
- Seventy-eight percent of patients had a mean hemoglobin $> 10\text{gm/dL}$ in the last quarter of 1998 compared to 69% of the patients in the last quarter of 1997, a nine percentage point increase from late 1997 to late 1998. (FIGURE 4)
- Seven percent of African-Americans and 4% of Caucasians were severely anemic (severe anemia for this report is defined as mean hemoglobin $< 9\text{ gm/dL}$) in October–December 1998 compared to 10% and 6%, respectively, in October–December 1997.

OPPORTUNITIES TO IMPROVE

- Twenty percent of patients did not have a mean $Kt/V \geq 1.2$ during the three-month study period.
- Forty-eight percent of patients prescribed Epoetin did not have a mean hemoglobin of 11–12 gm/dL during the three-month study period.
- Sixty-three percent of patients did not have a mean serum albumin $\geq 4.0\text{ gm/dL}$ (BCG method) or $\geq 3.7\text{ gm/dL}$ (BCP method) during the three-month study period.

NEXT STEPS:

Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2000 and 2001.

B. ADEQUACY OF HEMODIALYSIS

This section and sections C and D will consist of two parts: (1) CPM results from 18 ESRD Network areas for October–December 1998 (the serum albumin information described in Section E is not considered a CPM for this report); and (2) a comparison of CPM and core indicators results for October–December 1998 and previous study periods.

1. October–December 1998

Data to assess five hemodialysis adequacy CPMs were collected in 1999. The time period from which these data were abstracted was October–December 1998. Results for three of these CPMs are included in this report (Hemodialysis Adequacy CPMs I – III). Hemodialysis Adequacy CPMs IV-V, which pertain to a facility’s practice for post-dialysis blood draw timing and baseline total cell volume measurement of dialyzers intended for reuse (see Appendix 2 for a description of these two CPMs), were pilot tested during this data collection effort; results from this pilot test will be available in a Supplemental Report in early 2000.

The results for all Hemodialysis Adequacy CPMs apply to that group of patients in the sample who were prescribed dialysis three times per week and diagnosed with ESRD April 1, 1998, or earlier (n = 6,250).

Hemodialysis Adequacy CPM I — The patient’s delivered dose of hemodialysis is measured at least once per month.

FINDING: Eighty-seven percent of the targeted adult in-center hemodialysis patients sampled had documented measurements of hemodialysis adequacy (URR and/or Kt/V) for each month during the three-month study period (October–December 1998). These measurements were recorded in the patient’s chart, not calculated from individual data points. An additional 10% of the patients sampled had documented adequacy measurements for two out of the three months, and another two percent of the patients had documented adequacy measurements for one of the three months.

Hemodialysis Adequacy CPM II — The patient’s delivered dose of hemodialysis recorded in the patient’s chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula (for Kt/V) (23) or urea reduction ratio (URR).

FINDING: Ninety-nine percent of the targeted adult in-center hemodialysis patients had each monthly

delivered hemodialysis dose reported as either URR or Kt/V (reported as calculated using formal UKM or Daugirdas II formula).

Among the subset of patients for which a reported Kt/V value was entered on the data collection form, regardless of whether a URR measurement was also reported, only 47% of these Kt/V values were reported as being calculated by UKM or the Daugirdas II formula.

Hemodialysis Adequacy CPM III — The patient’s delivered dose of hemodialysis calculated from data points on the data collection form (monthly measurement averaged over the three-month study period) is either $Kt/V \geq 1.2$ or $URR \geq 65\%$.

FINDING: For the last quarter of 1998, 85% of the targeted adult in-center hemodialysis patients had a mean delivered hemodialysis dose of either $URR \geq 65\%$ or $Kt/V \geq 1.2$.

Other Hemodialysis Adequacy Findings

The mean delivered Kt/V for the national sample of adult in-center hemodialysis patients in the last quarter of 1998 was 1.40. The distribution of Kt/V values for these patients is shown in Figure 8a. The mean delivered URR was 68.2%; the distribution of delivered URR values is shown in Figure 8b. The mean Kt/V and URR values, and the percent of patients with mean $Kt/V \geq 1.2$, $Kt/V \geq 1.25$, and $URR \geq 65\%$ for gender, race/ethnicity, age, and diagnosis are shown in Table 5.

The percent of patients who received adequate hemodialysis, defined as a $Kt/V \geq 1.2$, approximately equivalent to $URR \geq 65\%$ (1,6) in the last quarter of 1998 was 80%. (TABLE 5) The percent of patients receiving hemodialysis with a mean $Kt/V \geq 1.2$ was higher for women than for men, higher for Caucasians than for African-Americans, higher for patients ≥ 65 years of age than for those 18-44 and 45-64 years of age, and higher for non-diabetics compared to diabetics. (TABLE 5, FIGURE 9)

The mean time spent on dialysis per dialysis session was 212 minutes. The mean time spent on dialysis was somewhat longer for men than for women (219 minutes vs. 204 minutes), and for African-Americans than for Caucasians (216 minutes vs. 209 minutes). The mean blood pump flow rate 60 minutes into the dialysis session was 399 mL/min for patients with an AVF, 406 mL/min for patients with either a synthetic or bovine graft, and 327 mL/min for patients with a

catheter access during October–December 1998. (FIGURE 10) Actual blood flows are usually much lower than blood pump blood flows. This is especially true with catheters, where a 25–30% decrease difference exists at blood pump Q_b greater than 300 mL/minute. (24)

The percent of patients who received adequate hemodialysis varied significantly from one geographic region to another. Table 6 shows, by race and gender, the percent of patients who received hemodialysis with a mean delivered $Kt/V \geq 1.2$ in each Network area; the percent ranged from 74% to 87%. (FIGURES 11, 12)

TABLE 5: Mean delivered Kt/V , mean delivered URR, and percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean $Kt/V \geq 1.2$, $Kt/V \geq 1.25$, and URR $\geq 65\%$, by patient characteristics, October–December 1998. 1999 ESRD CPM Project.

Patient Characteristics	Mean Kt/V	$Kt/V \geq 1.2$	$Kt/V \geq 1.25$	Mean URR (%)	URR $\geq 65\%$
TOTAL	1.40	80	74	68.2	74
GENDER					
Men	1.35	76	68	66.7	68
Women	1.47	86	82	70.1	82
RACE/ETHNICITY					
American Indian/ Alaska Native	1.49	84	82	69.9	80
Asian/Pacific Islander	1.51	88	83	70.8	82
African-American	1.37	78	71	67.2	70
Caucasian	1.42	81	76	68.7	76
Other/ Unknown	1.43	84	77	68.9	77
Hispanic	1.44	84	78	69.3	79
AGE GROUP (years)					
18–44	1.38	76	70	67.1	67
45–64	1.38	78	72	67.5	71
65+	1.43	84	79	69.4	80
DIAGNOSIS					
Diabetes mellitus	1.39	79	73	67.8	72
Hypertension	1.40	81	75	68.3	75
Glomerulonephritis	1.42	81	77	68.6	76
Other/Unknown	1.42	81	76	68.7	76
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)					
32.9–56.9	1.55	91	88	71.7	87
57.0–66.1	1.46	87	84	69.9	83
66.2–74.8	1.40	82	77	68.1	75
74.9–87.4	1.36	77	71	67.4	72
87.5–216.3	1.27	65	56	64.6	56

Note: Because convective clearance is not accounted for by the URR, the mathematical relationship between URR and Kt/V will vary. Caution is urged in extrapolating frequency distribution curves of dialysis adequacy using URR versus Kt/V . A delivered URR of 65% does not necessarily correlate with a delivered Kt/V of 1.2.

Figure 8a: Distribution of mean delivered Kt/V values for adult (aged ≥ 18 years) in-center hemodialysis patients, October–December 1998. 1999 ESRD CPM Project.

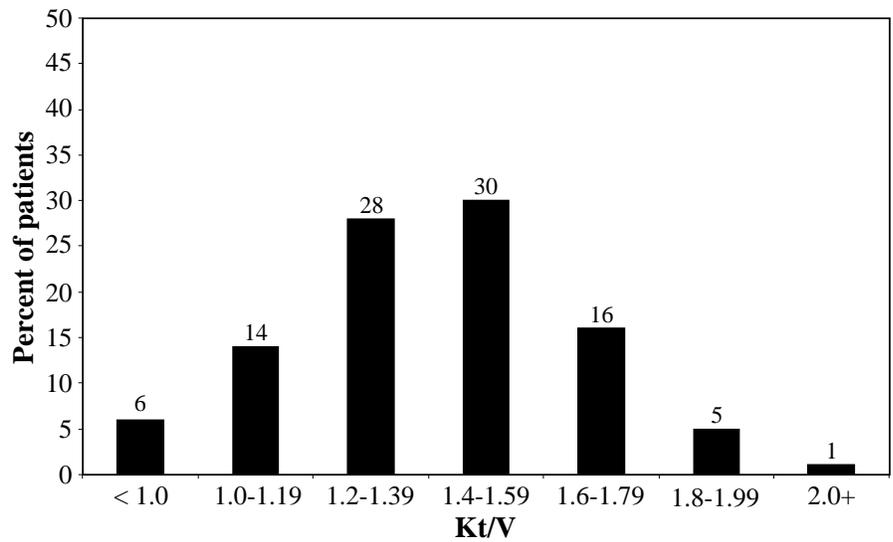


Figure 8b: Distribution of mean delivered URR values for adult (aged ≥ 18 years) in-center hemodialysis patients, October–December 1998. 1999 ESRD CPM Project.

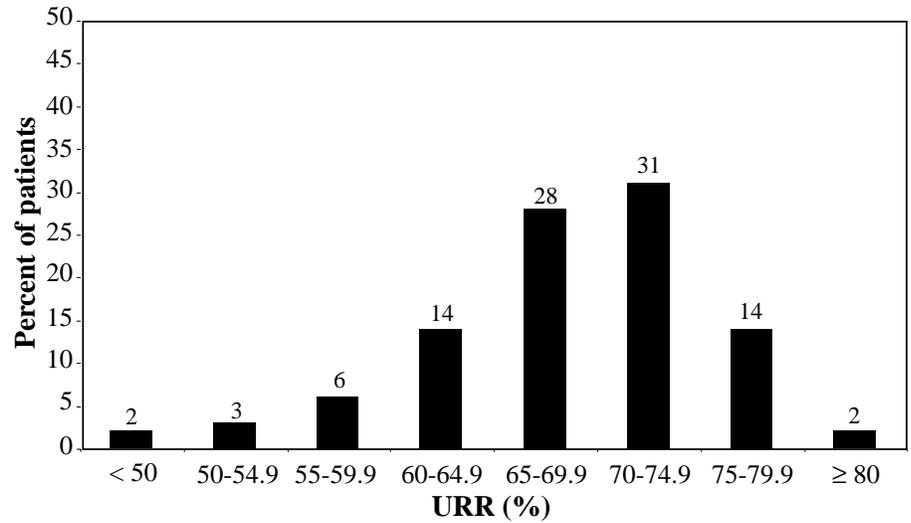


Figure 9: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean delivered Kt/V ≥ 1.2 , by race and gender, October–December 1998. 1999 ESRD CPM Project.

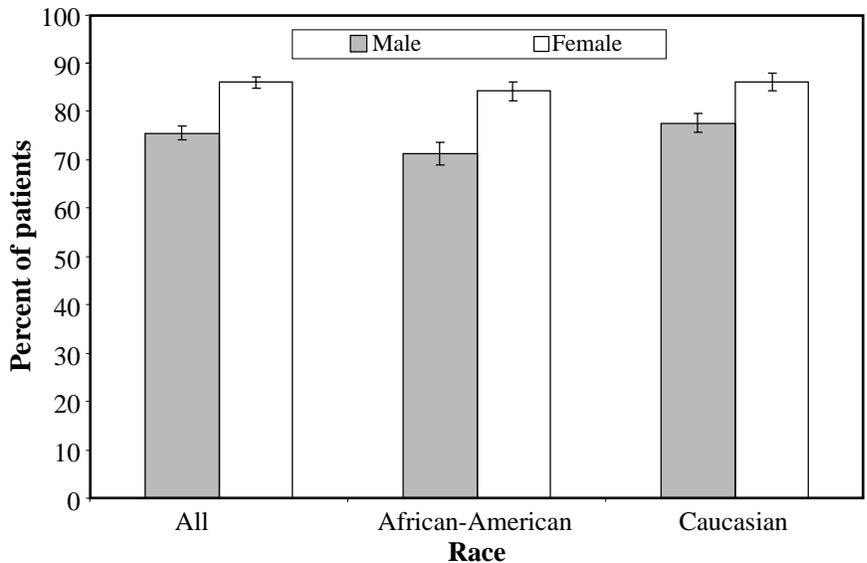


TABLE 6: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients receiving dialysis with a mean delivered $Kt/V \geq 1.2$, by gender, race, and Network, October–December 1998. 1999 ESRD CPM Project.

Patient Characteristic	Network																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	83	77	84	84	79	77	79	82	81	74	77	82	76	87	84	83	80	78	80	
RACE																				
African-American	81	74	82	84	82	77	76	81	79	71	73	75	74	81	78	75	73	74	78	
Caucasian	83	80	87	84	73	78	80	82	83	76	79	85	79	91	84	84	73	78	81	
MEN																				
African-American	79	70	83	77	77	67	66	77	74	62	63	67	70	74	71	79	66	64	71	
Caucasian	82	78	83	81	69	72	78	77	81	71	76	82	73	90	80	81	70	71	78	
WOMEN																				
African-American	82	80	80	92	88	86	86	85	83	79	84	84	78	88	84	70	81	87	84	
Caucasian	84	82	93	90	80	85	83	89	85	80	85	90	88	94	89	88	78	86	86	

Note: A delivered Kt/V of 1.2 does not necessarily correlate with a delivered URR of 65%.

Figure 10: Distribution of mean blood pump flow rates 60 minutes into the dialysis session for adult (aged ≥ 18 years) in-center hemodialysis patients, by current access type, October–December 1998. 1999 ESRD CPM Project.

Note: Actual blood flows are usually much lower than blood pump blood flows. This is especially true with catheters, where a 25-30% decrease difference exists at blood pump Q_b greater than 300 mL/minute. (24)

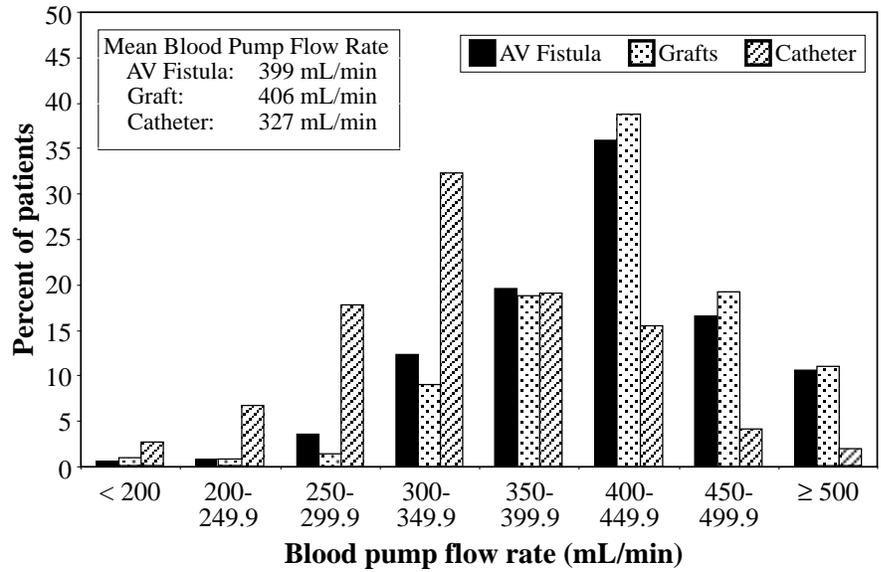


Figure 11: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients receiving dialysis with a mean delivered $Kt/V \geq 1.2$, by Network, October–December 1998. 1999 ESRD CPM Project.

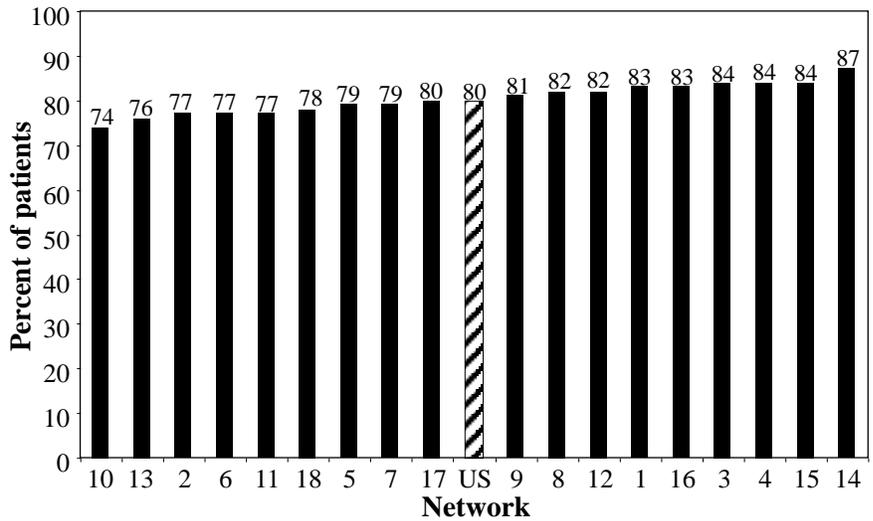
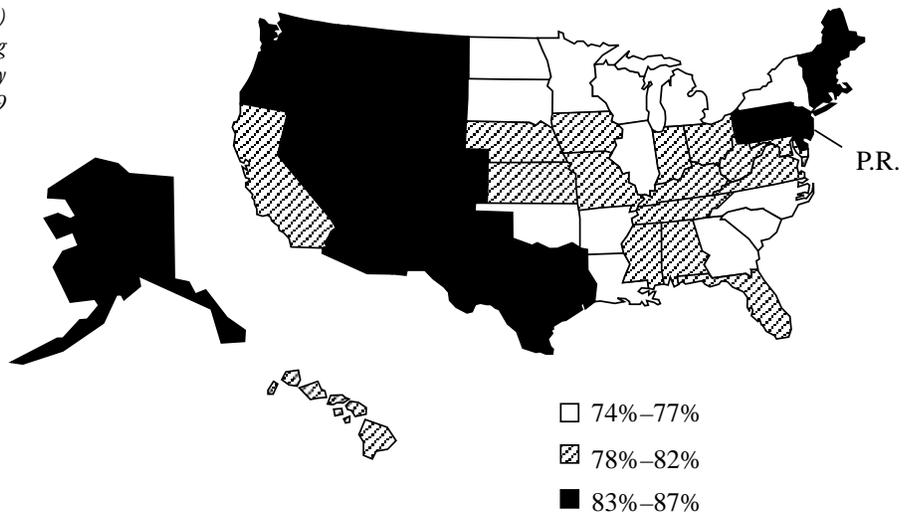


Figure 12: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients receiving dialysis with a mean delivered $Kt/V \geq 1.2$, by Network, October–December 1998. 1999 ESRD CPM Project.



2. October–December 1998 compared to previous study years

The average delivered Kt/V in October–December 1998 was 1.40, an increase from previous study years. The proportion of patients receiving dialysis with a mean delivered Kt/V ≥ 1.2 increased significantly from 78% in late 1997 to 80% in late 1998. (FIGURE 2) This significant improvement occurred for both Caucasian and African-American patients. (FIGURE 13a) Nationally, this improvement means that approximately 4,000 patients were receiving hemodialysis with a mean Kt/V ≥ 1.2 in late 1998 who would not have received

this level of dialysis had they been dialyzing one year earlier. (FIGURE 13a) Improvement in the proportion of patients with a mean delivered URR $\geq 65\%$ was also noted. (FIGURE 13b)

Figure 14 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer KUf category October–December 1998, compared to October–December 1993, 1994, 1995, 1996, and 1997.

Figure 15 shows a trend for slight increases in dialysis session lengths from late 1993 to late 1998.

Figure 13a: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean delivered Kt/V ≥ 1.2 , by race, October–December 1998 compared to October–December 1996 and 1997. 1999 ESRD CPM Project.

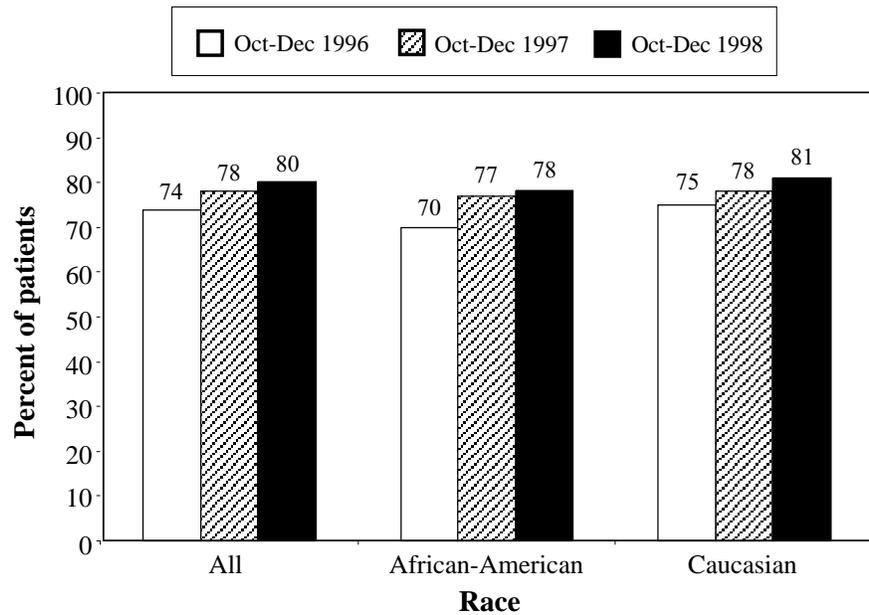
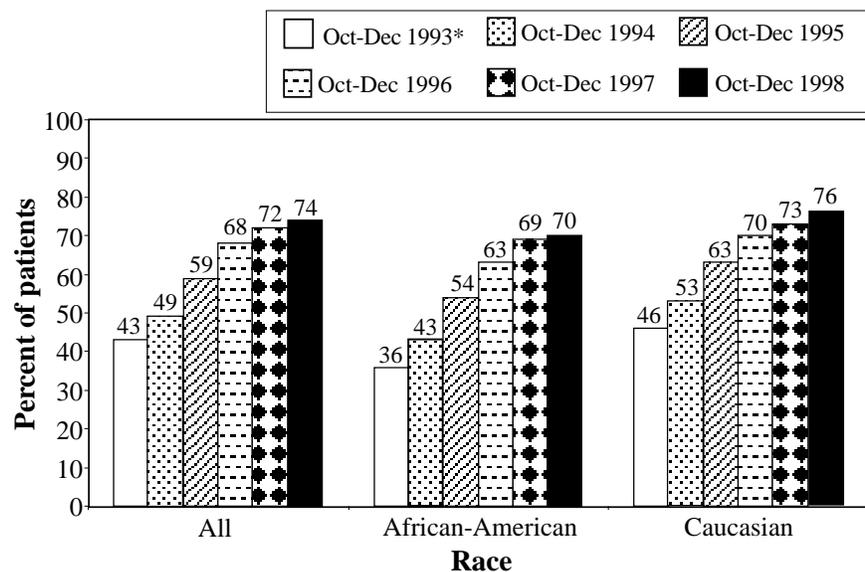
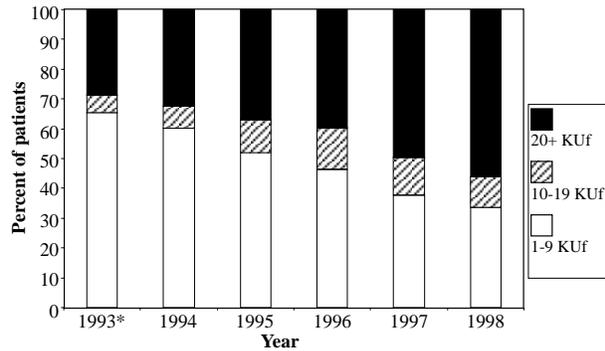


Figure 13b: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean delivered URR $\geq 65\%$, by race, October–December 1998 compared to October–December 1993*, 1994, 1995, 1996, and 1997. 1999 ESRD CPM Project.



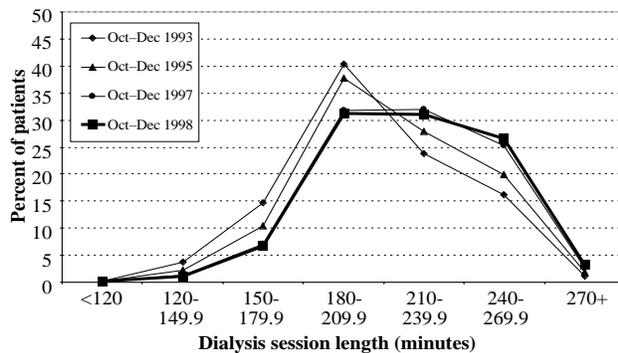
*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 14: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients dialyzed by dialyzer Kuf category, October–December 1998 compared to October–December 1993*, 1994, 1995, 1996, and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 15: Distribution of mean dialysis session length (minutes), October–December 1998 compared to October–December 1993*, 1995, and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

C. VASCULAR ACCESS

Data to assess four vascular access CPMs were collected in 1998. The time period from which these data were abstracted was October–December 1998. Results for three of these CPMs are included in this report. Complete results for the vascular access CPMs will be available in a Supplemental Report in early 2000.

Vascular Access CPM I — A primary arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of all prevalent patients undergoing hemodialysis.

FINDING: Twenty-six percent of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 1998, and August 31, 1998,

[n = 1,621]) were dialyzed using an AVF during October–December 1998. Twenty-six percent of prevalent patients were dialyzed using an AVF during October–December 1998.

Vascular Access CPM II — Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for 90 days or longer) as their permanent chronic dialysis access.

FINDING: Fourteen percent of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 1998.

Vascular Access CPM IV — A patient's AV graft should be routinely monitored for stenosis. (See Vascular Access CPM IV in Appendix 2 for a list of techniques and frequency of monitoring used to screen for the presence of stenosis.)

FINDING: Thirty-seven percent of patients with an AV graft had this graft routinely monitored for the presence of stenosis during October–December 1998.

D. ANEMIA MANAGEMENT

1. October–December 1998

Data to assess three anemia management CPMs were collected in 1999. The time period from which these data were abstracted was October–December 1998.

Anemia Management CPM I — The target hemoglobin is 11–12 gm/dL, and the target hematocrit is 33–36%. Patients with a mean hemoglobin > 12 gm/dL or mean hematocrit > 36% and not prescribed Epoetin were excluded from analysis for this CPM.

FINDING: For the last quarter of 1998, 52% of the targeted in-center hemodialysis patients had a mean hemoglobin between 11–12 gm/dL; 48% of patients had a mean hematocrit between 33–36%.

Anemia Management CPM II a — For all anemic patients (hemoglobin < 11 gm/dL or hematocrit < 33%) or patients prescribed Epoetin, the percent transferrin saturation and the serum ferritin concentration are assessed (measured) at least once in a three-month period.

FINDING: For the last quarter of 1998, 90% of the targeted in-center hemodialysis patients had at least one documented (measured) transferrin saturation value and at least one documented (measured) serum ferritin concentration value during the study period.

Anemia Management CPM II b — For all anemic patients (hemoglobin < 11 gm/dL or hematocrit < 33%) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation $\geq 20\%$ were documented during the three-month study period.

FINDING: For the last quarter of 1998, 67% of the targeted in-center hemodialysis patients had at least one documented transferrin saturation $\geq 20\%$ and at least one documented serum ferritin concentration ≥ 100 ng/mL during the study period.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 gm/dL or hematocrit < 33%), or patients prescribed Epoetin, and with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was $\geq 50\%$ or the mean serum ferritin concentration was ≥ 800 ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

FINDING: Sixty-three percent of the targeted in-center hemodialysis patients were prescribed intravenous iron in at least one month during October–December 1998.

Other Anemia Management Findings

The distributions of hemoglobin and hematocrit values are shown in Figures 16a and 16b, respectively, for both African-American and Caucasian patients. The mean hemoglobin value for patients in this sample was 11.1 gm/dL. The mean hemoglobin values for gender, race/ethnicity, age, and diagnosis are shown in Table 7. The mean hemoglobin value was lower for females, African-Americans, and patients 18-44 years old compared to males, Caucasians, and patients older than 44 years. The mean hematocrit for adult in-center hemodialysis patients in the US in the last quarter of 1998 was 34.3%.

The percent of patients with severe anemia (mean hemoglobin < 9 gm/dL) was 5%. The prevalence of severe anemia was higher in women compared to men, higher in patients 18-44 years of age compared to older patients and, as reported previously (25), higher in African-Americans than in Caucasians. The prevalence of severe anemia ranged from 2% to 8% among Networks. (FIGURE 17)

Tables 8a and 8b show, by Network, race, and age group, the percent of patients prescribed Epoetin with hemoglobin values 11–12 gm/dL, and

Figure 16a: Distribution of mean hemoglobin values for adult (aged ≥ 18 years) in-center hemodialysis patients in the US, by race, October–December 1998. 1999 ESRD CPM Project.

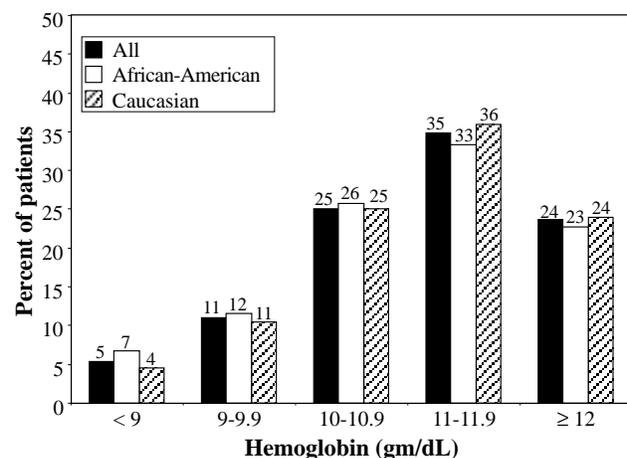
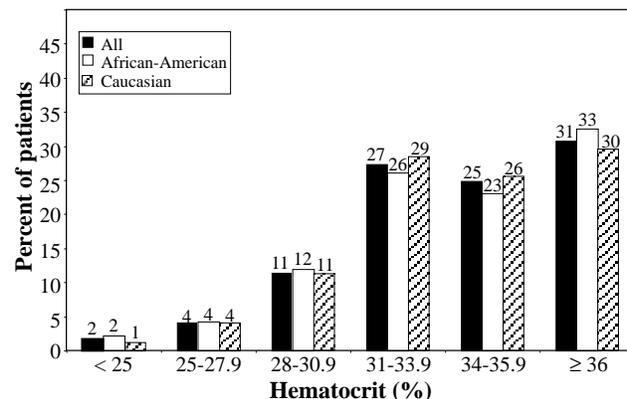


Figure 16b: Distribution of mean hematocrit values for adult (aged ≥ 18 years) in-center hemodialysis patients in the US, by race, October–December 1998. 1999 ESRD CPM Project.



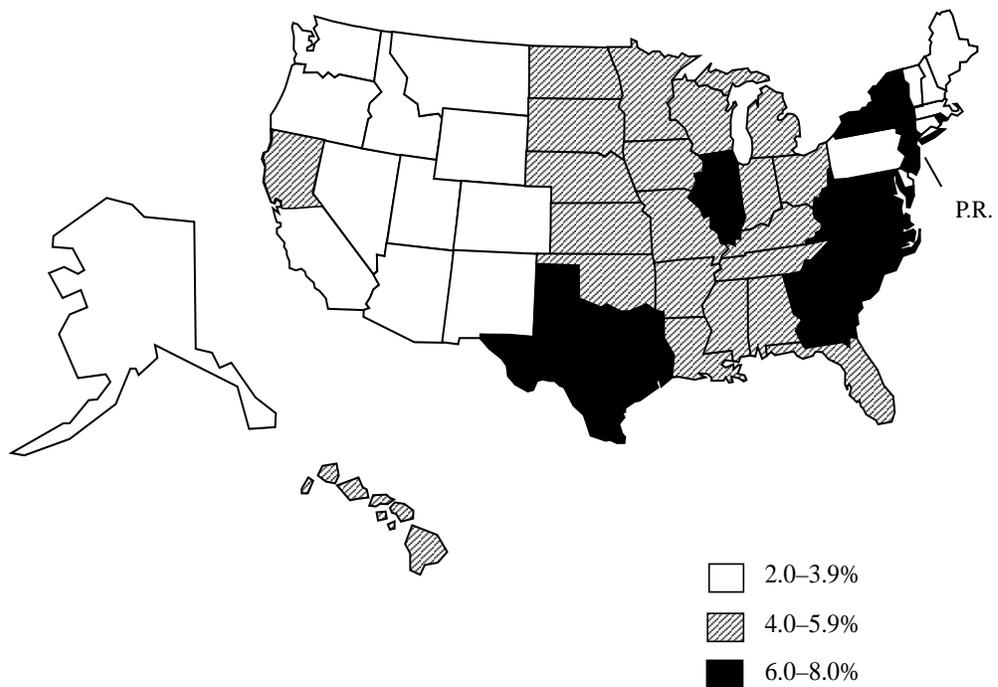
Note: The values appearing above the bars in the graph have been rounded; the bars, however, represent unrounded values.

TABLE 7: Hemoglobin values (gm/dL) for adult (aged ≥ 18 years) in-center hemodialysis patients in the US, by patient characteristics, October–December 1998. 1999 ESRD CPM Project.

Patient Characteristic	Mean Hemoglobin (gm/dL)	% of Patients with Hemoglobin Values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.1	5	11	25	35	24
GENDER						
Men	11.3	5	10	23	35	27
Women	11.0	6	12	28	35	20
RACE/ETHNICITY						
American Indian/ Alaska Native	11.4	3	8	24	31	34
Asian/Pacific Islander	11.3	2	11	22	41	24
African-American	11.1	7	12	26	33	23
Caucasian	11.2	4	10	25	36	24
Other/Unknown	11.2	6	11	23	35	25
Hispanic	11.2	4	10	24	35	26
AGE GROUP (years)						
18–44	11.1	9	10	22	33	25
45–64	11.2	5	12	26	32	25
65+	11.2	4	10	26	38	22
DIAGNOSIS						
Diabetes mellitus	11.1	5	11	26	34	24
Hypertension	11.1	6	11	25	36	22
Glomerulonephritis	11.2	4	12	24	35	25
Other/Unknown	11.2	6	10	23	36	25

Note: Percents may not add up to 100% due to rounding.

Figure 17: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean hemoglobin < 9 gm/dL, by Network, October–December 1998. 1999 ESRD CPM Project.



the percent of patients prescribed Epoetin with mean hematocrit 33%–36%, respectively. The percentages of all patients prescribed Epoetin with mean hemoglobin 11–12 gm/dL was 52% nationally and ranged from 38% to 60% by Network. (TABLE 8a) The percent of all patients prescribed Epoetin, by race and age group, with mean hemoglobin 11–12 gm/dL and mean hematocrit 33–36% are shown in Figures 18a and 18b, respectively. The percent of all patients with mean hemoglobin > 10 gm/dL was 78% nationally and ranged from 72% to 85% by Network. (FIGURE 19a) The percent of all patients with mean hemoglobin \geq 11 gm/dL was 59%

nationally and ranged from 50% to 68% by Network. (FIGURES 19b, 20)

Because patients could have Epoetin prescribed during one project month but not during another, we were not able to correlate Epoetin use with the mean hemoglobin values. Instead, we assessed Epoetin use at the time of each of the 22,647 hemoglobin determinations reported in this Project. Overall, Epoetin was prescribed 96% of the time when a hemoglobin value was determined.

During this study period, data were collected on additional measures useful for anemia management. (TABLE 9)

Figure 18a: Percent of adult (aged \geq 18 years) in-center hemodialysis patients prescribed Epoetin with mean hemoglobin 11–12 gm/dL, by age and race, October–December 1998. 1999 ESRD CPM Project.

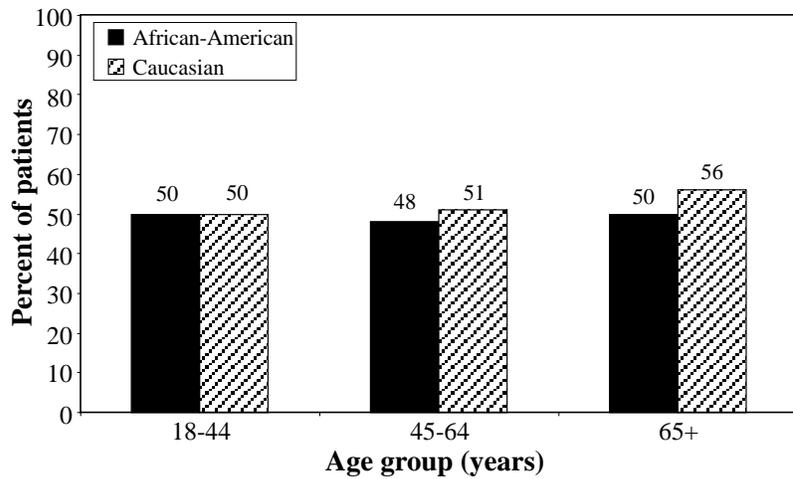


Figure 18b: Percent of adult (aged \geq 18 years) in-center hemodialysis patients prescribed Epoetin with mean hematocrit 33–36%, by age and race, October–December 1998. 1999 ESRD CPM Project.

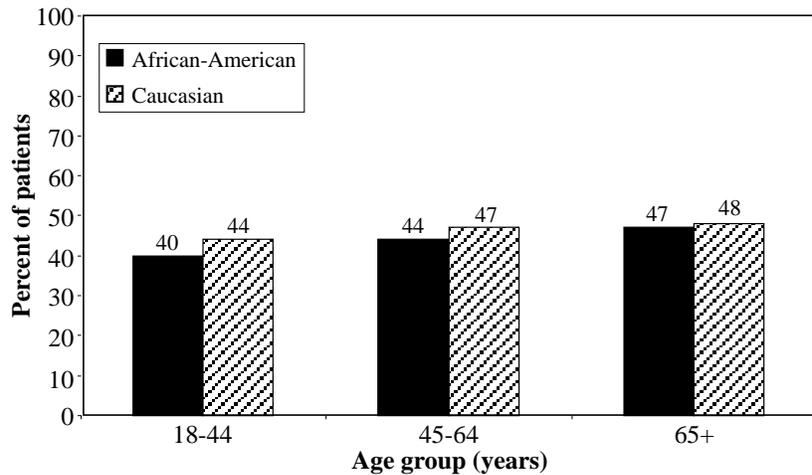


TABLE 8a: Percent of adult (aged ≥18 years) in-center hemodialysis patients prescribed Epoetin with mean hemoglobin 11–12 gm/dL, by age, race, and Network, October–December 1998, 1999 ESRD CPM Project.

Patient Characteristic	Network																		US
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
ALL	55	51	48	60	56	46	51	52	52	44	46	53	44	57	59	38	55	58	52
RACE																			
African-American	57	48	49	58	59	48	49	51	51	38	38	54	41	50	54	28	54	50	49
Caucasian	55	50	53	61	53	42	54	53	52	51	50	53	48	60	58	40	48	60	53
AGE GROUP (years)																			
18–44																			
African-American	*	42	47	48	53	62	48	59	56	35	28	58	45	50	*	*	40	*	50
Caucasian	53	50	57	62	*	*	54	*	43	73	48	38	39	58	59	43	46	54	50
45–64																			
African-American	53	49	47	57	52	46	58	48	54	40	38	52	38	49	*	*	59	55	48
Caucasian	53	57	58	52	50	35	58	56	49	46	44	49	41	54	54	37	44	60	51
65+																			
African-American	68	50	53	64	67	42	40	49	45	39	46	56	42	51	73	*	64	49	50
Caucasian	57	46	50	65	56	54	51	54	55	50	54	58	56	68	61	41	52	62	56

*Value suppressed because n < 10

TABLE 8b: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients prescribed Epoetin with mean hematocrit 33–36%, by age, race, and Network, October–December 1998, 1999 ESRD CPM Project.

Patient Characteristic	Network																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	44	48	41	46	50	43	47	43	46	42	45	46	40	45	48	54	48	52	46
RACE																			
African-American	50	43	45	44	52	45	46	41	46	43	38	40	36	43	43	53	46	43	44
Caucasian	43	54	42	47	48	40	48	47	45	44	48	51	48	44	49	55	45	50	47
AGE GROUP (years)																			
18–44																			
African-American	*	40	40	42	42	43	52	44	38	33	33	*	27	32	*	*	*	50	39
Caucasian	*	54	*	50	59	*	48	*	32	54	52	41	39	50	41	59	*	42	44
45–64																			
African-American	56	43	41	47	54	45	52	41	47	44	36	33	33	49	*	*	41	38	44
Caucasian	54	64	42	40	47	45	47	49	41	41	46	48	44	39	45	53	44	52	47
65+																			
African-American	56	47	54	42	56	45	37	39	48	48	44	50	44	45	*	52	64	46	47
Caucasian	40	48	44	51	46	38	48	45	51	43	49	55	54	47	56	56	49	51	48

*Y value suppressed because n < 10

Figure 19a: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean hemoglobin > 10 gm/dL, by Network, October–December 1998. 1999 ESRD CPM Project.

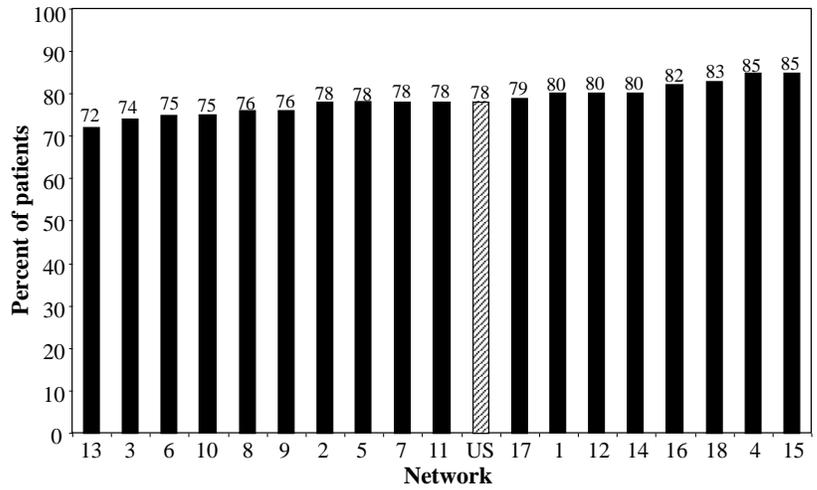


Figure 19b: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by Network, October–December 1998. 1999 ESRD CPM Project.

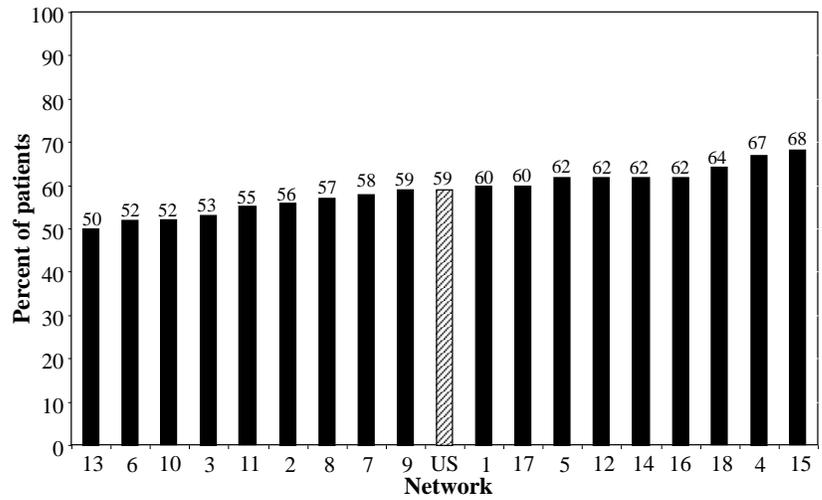


Figure 20: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by Network, October–December 1998. 1999 ESRD CPM Project.

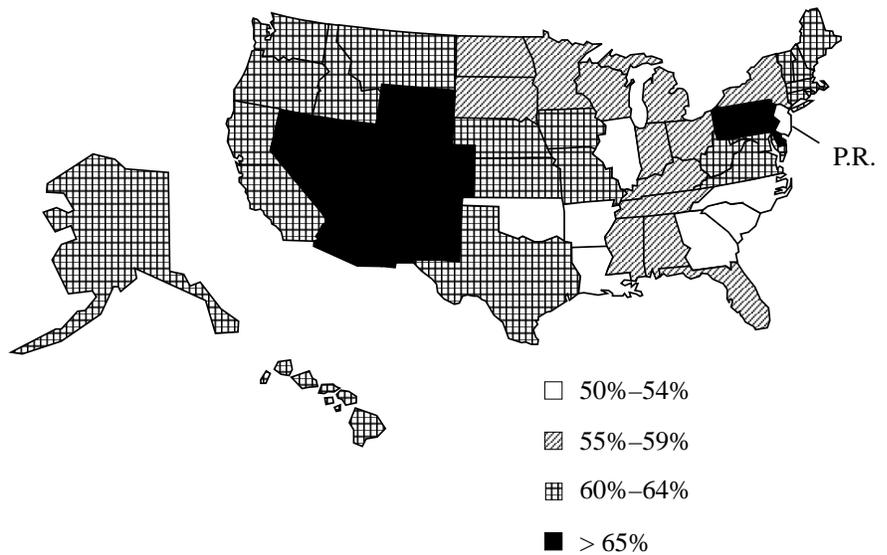


TABLE 9: Regional variation for various anemia management measures for adult (aged ≥ 18 years) in-center hemodialysis patients, and the percent of patients with mean hemoglobin ≥ 11 gm/dL, mean hematocrit $\geq 33\%$, and mean serum albumin ≥ 4.0 gm/dL[^], and the mean hemoglobin (gm/dL) for these patients nationally and by Network, October–December 1998. 1999 ESRD CPM Project.

Anemia Management Measure	Network																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
Percent of patients with mean hemoglobin ≥ 11 gm/dL	60	56	53	67	62	52	58	57	59	52	55	62	50	62	68	62	60	64	59
Mean hemoglobin (gm/dL)	11.2	11.0	11.0	11.3	11.1	11.0	11.2	11.0	11.1	11.1	11.1	11.2	10.9	11.2	11.5	11.3	11.2	11.3	11.1
Percent of patients with mean hematocrit $\geq 33\%$	62	65	62	69	67	62	66	62	67	60	60	69	59	68	72	70	67	71	65
Percent of patients with mean serum albumin ≥ 4.0 gm/dL [^]	38	42	33	37	39	32	40	39	38	35	31	29	35	32	36	27	42	34	36
Average transferrin saturation (%)	28.1	28.4	29.3	19.4	29.3	30.1	30.4	32.6	20.6	24.6	28.8	27.3	30.4	29.5	28.1	27.9	26.4	30.2	28.0
Percent of patients with transferrin saturation $\geq 20\%$	70	69	66	45	74	75	73	64	41	62	66	59	65	79	63	66	66	72	66
Average serum ferritin concentration (ng/mL)	433	424	522	218	440	526	539	499	267	323	448	470	488	503	540	494	513	546	455
Percent of patients with serum ferritin concentration ≥ 100 ng/mL	77	74	78	58	77	78	84	83	73	73	80	79	81	81	82	82	85	86	78
Percent of patients with IV iron prescribed	56	46	58	62	50	63	55	55	70	60	60	60	68	59	59	66	59	60	59
Percent of patients * with subcutaneous Epoetin prescribed	9	7	7	9	2	6	5	7	29	14	17	23	12	17	5	19	11	9	12 [^]

[^]For subset of patients with serum albumin tested by the bromocresol green (BCG) laboratory method

*Among patients prescribed Epoetin

The national average transferrin saturation for the patients in the sample was 28.0% and ranged from 19.4% to 32.6% among the 18 Network areas. (TABLE 9) Table 9 also provides the percent of patients with mean transferrin saturation $\geq 20\%$ nationally (66%) and by Network area, ranging from 41% to 79%.

The national average serum ferritin concentration for the patients in the sample was 455 ng/mL and ranged from 218 to 546 ng/mL among the 18 Network areas. The percent of patients with a mean serum ferritin concentration ≥ 100 ng/mL nationally was 78%, ranging from 58% to 86%. (TABLE 9)

Seventy-two percent of patients were prescribed either intravenous (IV) or oral iron at least once during the three-month study period. The percent of patients with IV iron prescribed nationally was 59%, ranging from 46% to 70% among the 18 Network areas. (TABLE 9)

For the subset of patients with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL (n = 687 or 8% of sampled patients), only 52% were prescribed IV iron at least once during the three-month study period.

Of the patients prescribed Epoetin, 89% were prescribed Epoetin by the IV route; and 12% by the subcutaneous route (groups not mutually exclusive). Prescribed subcutaneous administration, the route recommended by the NKF DOQI Clinical Practice Guidelines for the treatment of anemia, (8) ranged from 2% to 29% among the 18 Network areas. (TABLE 9)

Table 10 depicts the odds ratio (95% CI) for experiencing a mean hemoglobin < 11 gm/dL by several patient and clinical characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a female has a 1.4 (or 40%) greater chance of experiencing a mean hemoglobin < 11 gm/dL than a male (without controlling for any other variables).

Table 10: Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for mean hemoglobin < 11 gm/dL. 1999 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
Gender	
Female	1.4 (1.3, 1.5)
Male (referent)	
Race	
African-American	1.2 (1.1, 1.3)
Caucasian (referent)	
Age group (years)	
18-44	1.03 (0.92, 1.2)
45+ (referent)	
Diabetes mellitus status	
DM+	1.06 (0.96, 1.2)
DM- (referent)	
Mean Kt/V	
< 1.2	1.8 (1.6, 2.0)
≥ 1.2 (referent)	
Mean serum albumin	
$< 3.5 / < 3.2$ gm/dL (BCG/BCP)*	2.6 (2.4, 3.0)
$\geq 3.5 / \geq 3.2$ gm/dL (BCG/BCP) (referent)	
Mean transferrin saturation	
$< 20\%$	1.8 (1.6, 2.0)
$\geq 20\%$ (referent)	
Mean serum ferritin concentration	
< 100 ng/mL	1.2 (1.1, 1.4)
≥ 100 ng/mL (referent)	

*BCG = bromocresol green laboratory method; BCP = bromocresol purple laboratory method

2. October–December 1998 compared to previous study periods

The average hemoglobin from October–December 1997 to October–December 1998 increased from 10.7 gm/dL to 11.1 gm/dL, and the percentage of patients with a mean hemoglobin > 10 gm/dL increased significantly from 69% to 78%. (FIGURES 4, 5a, 21a) The percent of patients with a mean hematocrit > 30% has increased from 1993 to 1998 for both African-Americans and Caucasians. (FIGURE 21b)

In addition to the improvement in the percentage of patients with mean hemoglobin > 10 gm/dL and mean hemoglobin \geq 11 gm/dL (FIGURE 22), there was also a decrease in the percentage of patients with severe anemia (mean hemoglobin < 9 gm/dL). In October–December 1997, 10% of African-American patients and 6% of Caucasian patients had severe anemia, while in

October–December 1998, 7% of African-American patients and 4% of Caucasian patients had severe anemia.

Figure 23 depicts the trend in Epoetin dosing (units/kg) from late 1997 to late 1998. In both years, subcutaneous Epoetin doses were systematically lower than the intravenous Epoetin doses at all hemoglobin categories examined.

Figure 24 depicts the status of iron stores for the sampled patients in late 1998 compared to late 1996 and late 1997. Overall, 59% of patients were prescribed IV iron in late 1998 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 52% of patients were prescribed IV iron at least once over the three-month study period in late 1998, compared to 40% in late 1997 and 37% in late 1996.

Figure 21a: Percent of adult (aged \geq 18 years) in-center hemodialysis patients with mean hemoglobin values > 10 gm/dL, by race, October–December 1998 compared to October–December 1997. 1999 ESRD CPM Project.

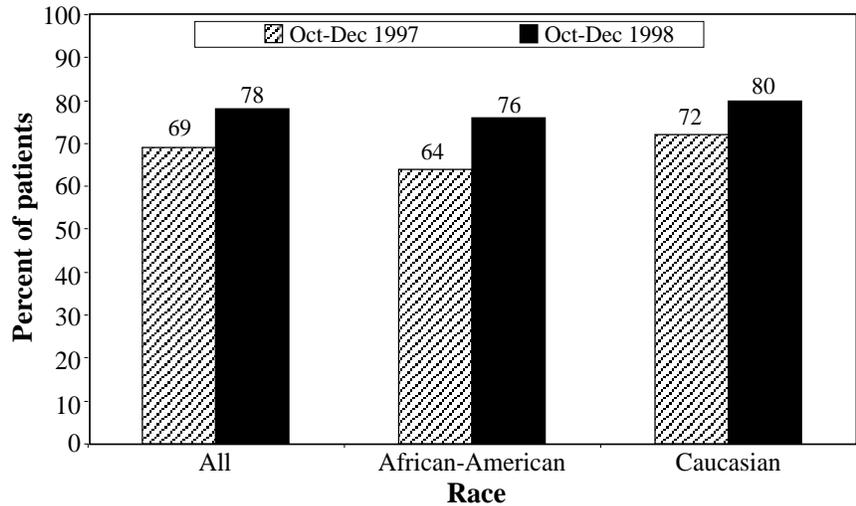
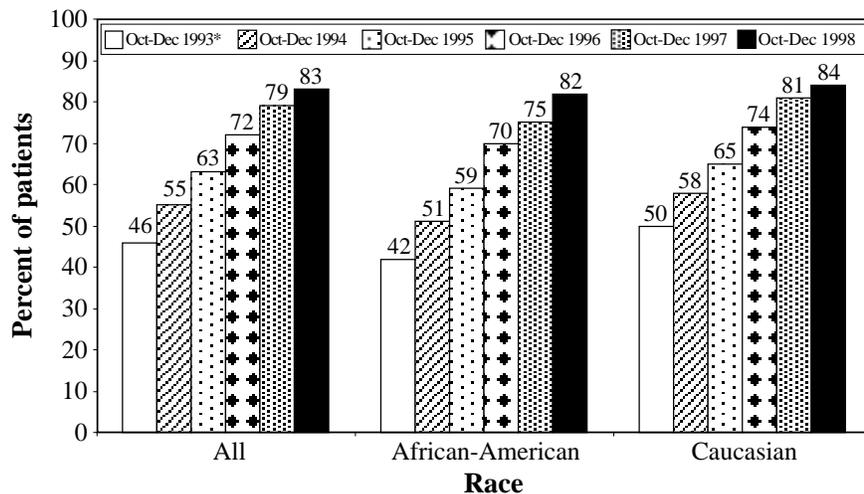


Figure 21b: Percent of adult (aged \geq 18 years) in-center hemodialysis patients with mean hematocrit > 30%, by race, October–December 1998 compared to October–December 1993*, 1994, 1995, 1996, and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Figure 22: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by race, October–December 1998 compared to October–December 1997. 1999 ESRD CPM Project.

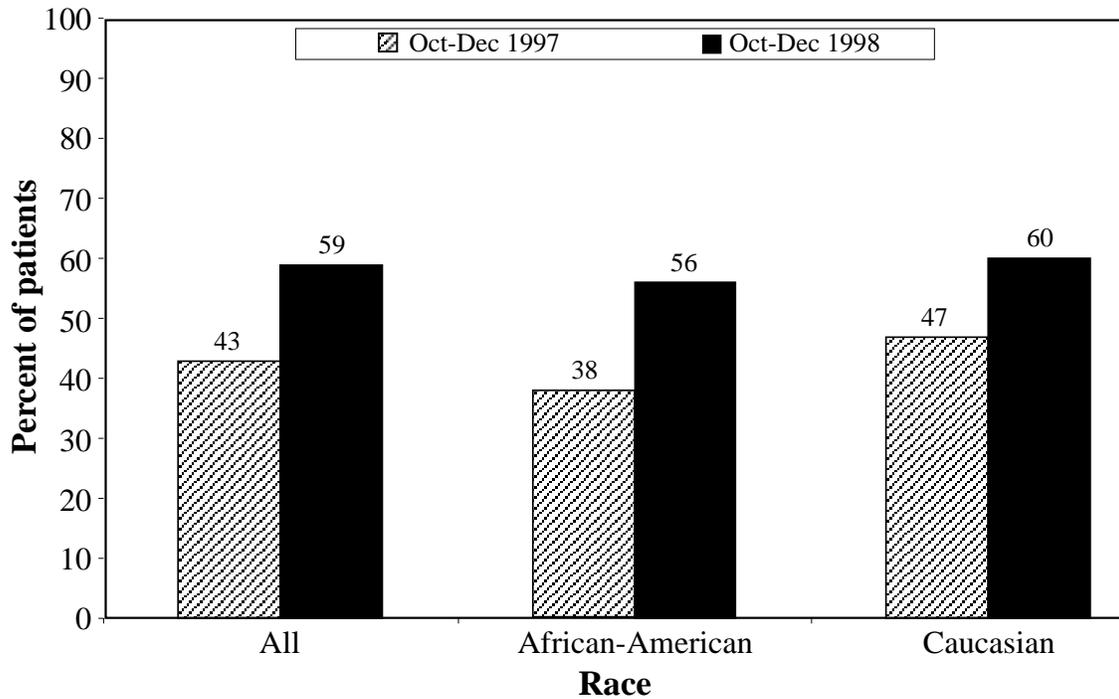


Figure 23: Mean Epoetin dose (units/kg) for adult (aged ≥ 18 years) in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 1998 compared to October–December 1997. 1999 ESRD CPM Project.

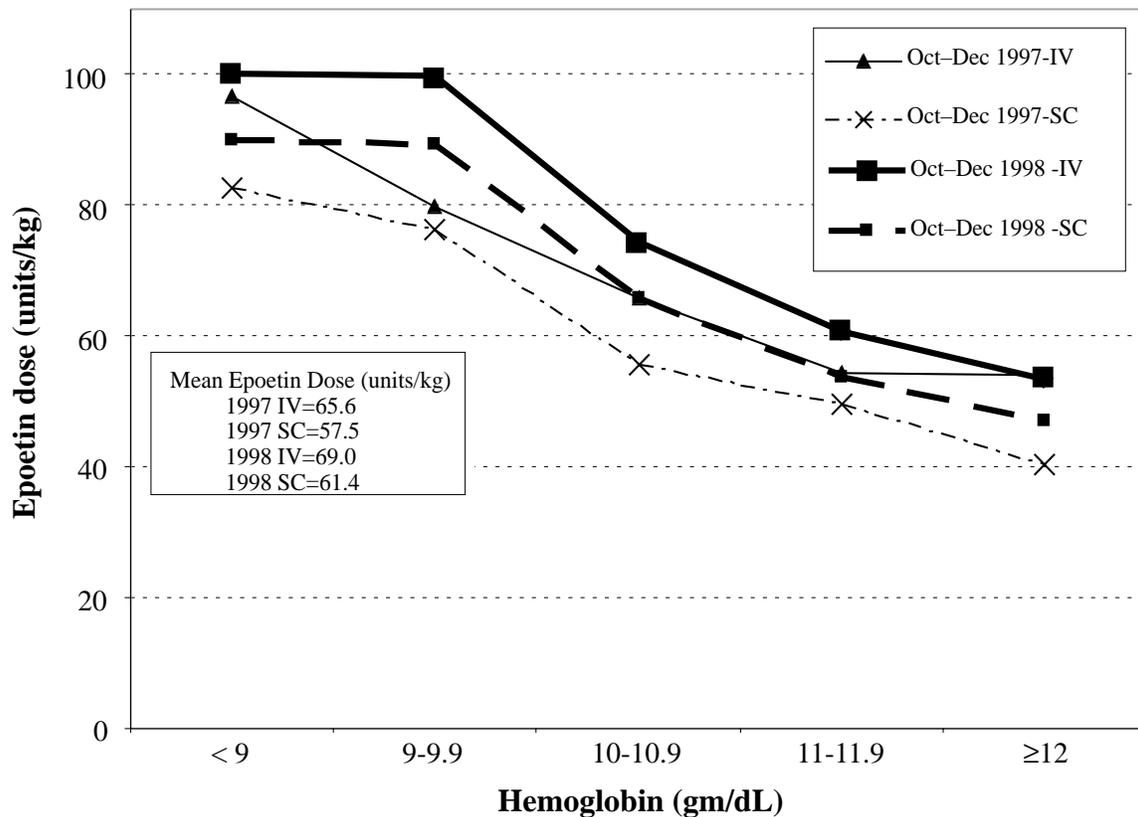
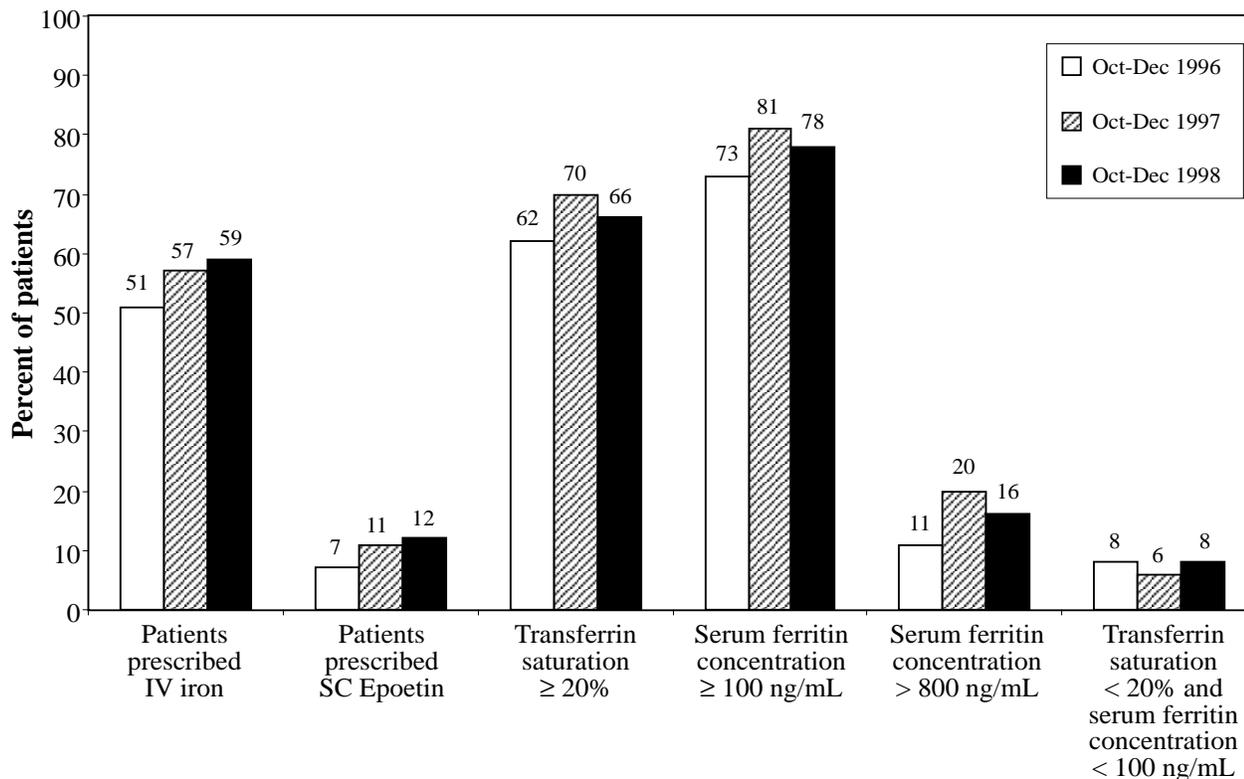


Figure 24: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients prescribed intravenous iron or subcutaneous Epoetin, with mean transferrin saturation $\geq 20\%$, mean serum ferritin concentration ≥ 100 ng/mL and > 800 ng/mL, and with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL, October–December 1996 compared to October–December 1998 and 1997. 1999 ESRD CPM Project.



E. SERUM ALBUMIN

1. October–December 1998

The two commonly used laboratory methods for determining serum albumin values, bromocresol green (BCG) and bromocresol purple (BCP), have been reported to yield systematically different results. (17) Therefore, we assessed the serum albumin values reported for these two methods separately. As expected, the values determined by the BCP method were systematically lower than those determined by the BCG method. (TABLE 11)

The mean serum albumin value for patients whose value was determined by the BCG method ($n = 6,987$) was 3.8 gm/dL, and by the BCP method ($n = 1,320$) was 3.6 gm/dL. The mean serum albumin values for gender, race/ethnicity, age, and diagnosis groups are shown in Table 11.

Mean serum albumin < 3.5 gm/dL by the BCG method was defined as an indicator of inadequate serum albumin. (26) Since the percent of mean serum albumin < 3.2 gm/dL by the BCP method was nearly

the same as the percent of serum albumin values < 3.5 gm/dL by the BCG method, we also defined a mean BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. “Optimal” serum albumin was defined as ≥ 4.0 gm/dL by the BCG method or ≥ 3.7 gm/dL by the BCP method. Figure 25 displays the distribution of serum albumin values by laboratory method.

Table 11 also shows the percent of patients by gender, race/ethnicity, age, and diagnosis groups with mean serum albumin ≥ 3.5 gm/dL by the BCG method or ≥ 3.2 gm/dL by the BCP method. The percent of patients with mean serum albumin ≥ 3.5 gm/dL by the BCG method or ≥ 3.2 gm/dL by the BCP method tended to be higher for African-Americans than for Caucasians, higher for men than for women, and higher for patients 18-44 years old than for patients 45 years or older. (TABLE 11, FIGURE 26a) The percent of patients in each Network area, by race and age group, with mean serum albumin ≥ 3.5 gm/dL by BCG method or ≥ 3.2 gm/dL by BCP method is shown in Table 12; the percent ranged from 72% to 85%. Nationally, 82% of patients had mean

serum albumin ≥ 3.5 gm/dL by the BCG method, or ≥ 3.2 gm/dL by the BCP method.

Thirty-seven percent of patients had mean serum albumin ≥ 4.0 gm/dL by the BCG method, or ≥ 3.7 gm/dL by the BCP method. The percent of patients with mean serum albumin ≥ 4.0 gm/dL by the BCG method, or ≥ 3.7 gm/dL by the BCP method, tended to be higher for African-Americans than for Caucasians, and for men than for women. (FIGURE 26b) The percent of patients with “optimal” serum albumin ranged from 23% to 42% among the 18 Networks.

2. October–December 1998 compared to previous study periods

There was no clinically important change or improvement in the proportion of adult in-center hemodialysis patients with adequate serum albumin levels during October–December 1998 compared to previous study periods.

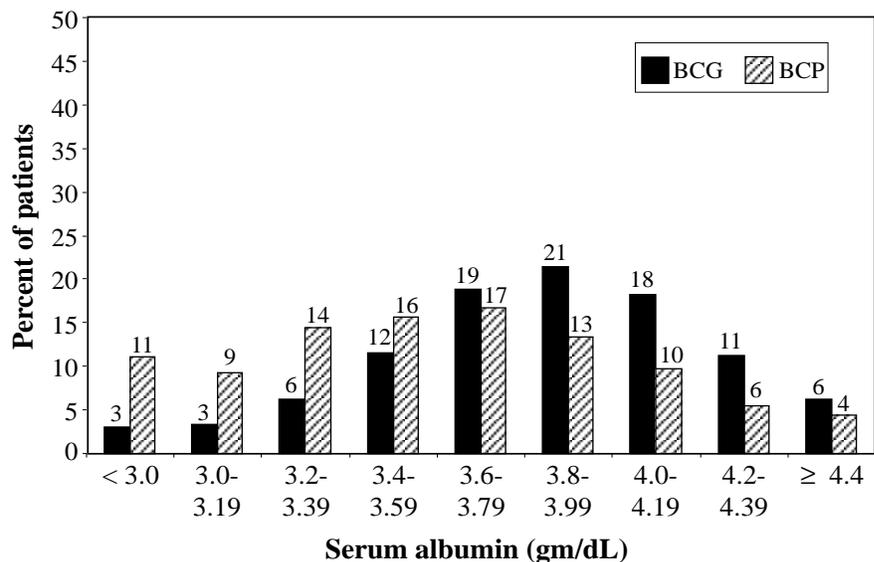
Figure 27 shows the percent of patients with mean serum albumin ≥ 3.5 gm/dL by the BCG method or ≥ 3.2 gm/dL by the BCP method during October–December 1998 compared to October–December 1993, 1994, 1995, 1996, and 1997.

TABLE 11: Mean serum albumin (gm/dL) for adult (aged ≥ 18 years) in-center hemodialysis patients in the US, by patient characteristics and by laboratory method*, October–December 1998. 1999 ESRD CPM Project.

Patient Characteristic	BCG		BCP	
	Mean	% ≥ 3.5 gm/dL	Mean	% ≥ 3.2 gm/dL
TOTAL	3.8	83	3.6	80
GENDER				
Men	3.9	84	3.6	82
Women	3.8	81	3.5	77
RACE/ETHNICITY				
American Indian/Alaska Native	3.7	76	3.4	67
Asian/Pacific Islander	3.9	85	3.6	88
African-American	3.8	85	3.6	81
Caucasian	3.8	81	3.5	77
Other/Unknown	3.8	80	3.7	85
Hispanic	3.8	85	3.6	88
AGE GROUP (years)				
18–44	4.0	87	3.7	90
45–64	3.8	83	3.6	81
65+	3.8	81	3.5	75
DIAGNOSIS				
Diabetes mellitus	3.8	79	3.5	74
Hypertension	3.9	87	3.7	89
Glomerulonephritis	3.9	85	3.7	88
Other/Unknown	3.8	83	3.5	75

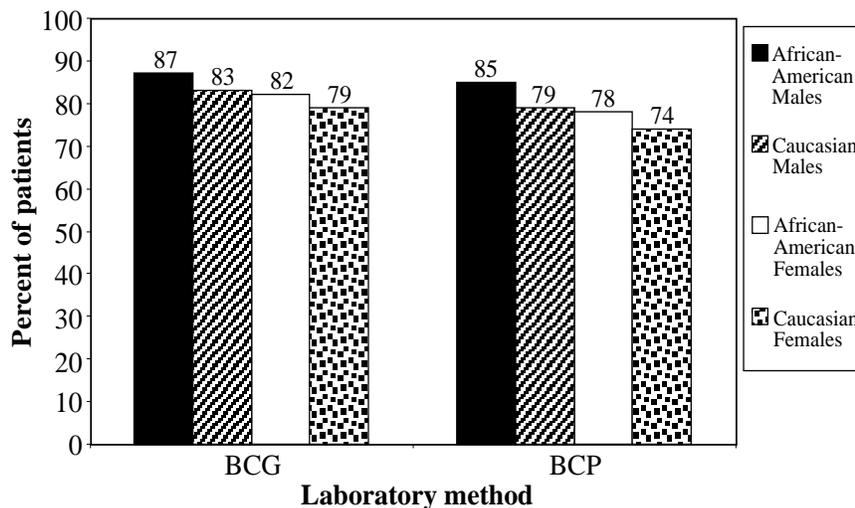
*Laboratory methods: BCG = bromcresol green; BCP = bromcresol purple

Figure 25: Distribution of mean serum albumin for adult (aged ≥ 18 years) in-center hemodialysis patients, by laboratory method*, October–December 1998. 1999 ESRD CPM Project.



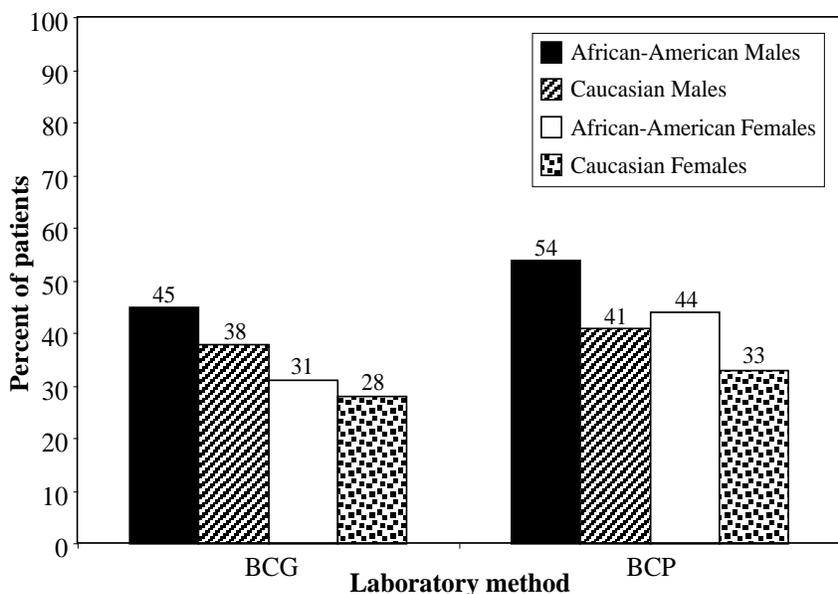
Note: BCG = bromcresol green; BCP = bromcresol purple

Figure 26a: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), by race and gender, October–December 1998. 1999 ESRD CPM Project.



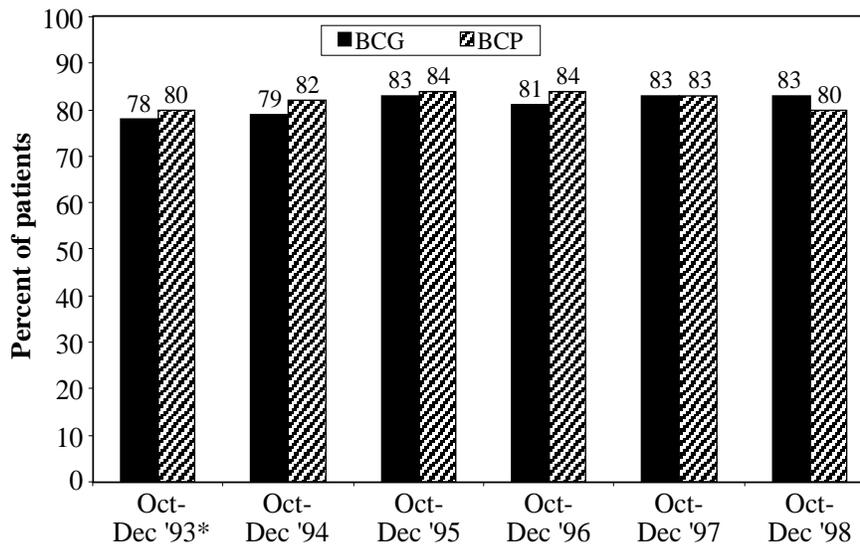
Note: BCG = bromcresol green; BCP = bromcresol purple

Figure 26b: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method), by race and gender, October–December 1998. 1999 ESRD CPM Project.



Note: BCG = bromcresol green; BCP = bromcresol purple

Figure 27: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), October–December 1998 compared to October–December 1993*, 1994, 1995, 1996, and 1997. 1999 ESRD CPM Project.



*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

Note: BCG = bromcresol green; BCP = bromcresol purple

TABLE 12: Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), by age, race, and Network, October–December 1998. 1999 ESRD CPM Project.

Patient Characteristic	Network																		US
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
ALL	83	82	80	81	83	84	85	84	81	81	77	78	82	84	83	72	84	85	82
RACE																			
African-American	90	86	85	83	84	86	85	84	87	83	80	83	84	80	82	62	80	89	84
Caucasian	82	77	81	79	82	77	84	84	78	79	76	76	80	88	85	74	86	85	81
AGE GROUP (years)																			
18–44																			
African-American	94	80	93	85	84	93	86	90	85	85	81	90	91	87	*	*	82	100	87
Caucasian	97	92	96	81	94	71	85	100	81	86	88	85	87	96	95	78	88	91	88
45–64																			
African-American	95	88	87	83	83	86	85	86	92	87	82	78	84	85	93	62	83	83	86
Caucasian	78	75	83	81	80	76	85	74	73	75	74	73	72	89	85	75	88	85	80
65+																			
African-American	82	84	78	83	84	81	84	80	83	76	79	88	79	67	88	57	74	89	81
Caucasian	81	74	77	78	81	80	84	89	80	79	76	75	83	84	80	72	84	82	80

*Value suppressed because n < 10

VII. PERITONEAL DIALYSIS PATIENTS

A. SYNOPSIS

- Purpose of Project: The ultimate purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in improving the care provided to ESRD patients. The specific purposes of the 1999 project were:

To compare the prevalence of important clinical characteristics of adult (aged ≥ 18 years) peritoneal dialysis patients in the US in October 1998–March 1999 to the prevalence of those characteristics in November 1994–April 1995; November 1995–April 1996; November 1996–April 1997; and November 1997–April 1998; AND, to identify opportunities to improve care for those patients.

- Method Used: A national random sample of adult peritoneal dialysis patients who were alive on December 31, 1998, was selected (sample size 1,650).

ESRD facilities, with assistance from ESRD Networks, submitted to PRO-West clinical information about these patients for the time period October 1998–March 1999 for aggregation. This aggregated data file was then forwarded to HCFA for initial analysis.

- Initial Findings: The sample for analysis consisted of 1,533 patients, which was 93% of the original sample. Highlights from the initial findings are summarized below.

IMPROVEMENT OCCURRED

- Adequacy of dialysis was assessed at least once for approximately 85% of the sampled patients during the 1999 study period (October 1998–March 1999), compared to 81% during the 1998 study period (November 1997–April 1998). (FIGURE 28)

- There was an improvement in the delivered adequacy of dialysis for sampled patients as measured by weekly Kt/V_{urea} and weekly creatinine clearance values during the 1998 study period compared to the 1996 and 1997 study periods. (FIGURES 7a, 7b, 29a, 29b; TABLE 13)
- There was a six percentage point increase in the percentage of peritoneal dialysis patients with mean hemoglobin > 10 gm/dL from the 1998 study period (76%) to the 1999 study period (82%).

OPPORTUNITIES TO IMPROVE

- The adequacy of dialysis was not assessed during the 1999 study period for an estimated 15% of the sampled peritoneal dialysis patients.
- A substantial percentage of sampled patients did not have weekly adequacy values meeting the Peritoneal Dialysis Adequacy CPM III.
- Forty-eight percent of the sampled peritoneal dialysis patients prescribed Epoetin did not have a mean hemoglobin 11–12 gm/dL in the 1999 study period.
- Forty-one percent of the sampled peritoneal dialysis patients did not have mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method) in the 1999 study period.
- Eighty-two percent of the sampled peritoneal dialysis patients did not have mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method) in the 1999 study period.

NEXT STEPS:

Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2000 and 2001.

B. ADEQUACY OF PERITONEAL DIALYSIS

This section and section C will consist of two parts: (1) CPM results from 18 ESRD Network areas for October 1998–March 1999 (serum albumin described in Section D is not considered a CPM for this report); (2) a comparison of CPM and core indicators results for October 1998–March 1999 and previous study periods.

1. October 1998–March 1999

Data to assess three peritoneal dialysis adequacy CPMs were collected in 1999. The time period from which these data were abstracted was October 1998–March 1999.

Peritoneal Dialysis Adequacy CPM I — The patient's total solute clearance for urea and creatinine is measured routinely (defined for this report as at least once during the six-month study period).

FINDING: Eighty-two percent of the sampled adult peritoneal dialysis patients had both a weekly Kt/V_{urea} and a weekly creatinine clearance measurement reported at least once during the six-month study period.

Peritoneal Dialysis Adequacy CPM II — The patient's total solute clearance for urea (weekly Kt/V_{urea}) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 2.)

FINDING: Fifty-five percent of the sampled adult peritoneal dialysis patients who had reported adequacy measurements documented in their chart at least once during the six-month study period had these reported measurements calculated (Kt/V_{urea} and creatinine clearance) in a standard way as described in Peritoneal Dialysis Adequacy CPM II in Appendix 2.

Peritoneal Dialysis Adequacy CPM III — For patients on CAPD, the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.0 and a weekly creatinine clearance of at least 60 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For cycler patients without a daytime dwell, the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.2 and a weekly creatinine clearance of at least 66 L/week/1.73 m², OR there was evidence the dialysis prescription was changed if the adequacy measurements

were below these thresholds during the six-month study period.

For cycler patients with a daytime dwell, the delivered peritoneal dialysis dose is a weekly Kt/V_{urea} of at least 2.1 and a weekly creatinine clearance of at least 63 L/week/1.73 m², OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: Fifty-five percent of CAPD patients had a mean weekly $Kt/V_{\text{urea}} \geq 2.0$ and a mean weekly creatinine clearance ≥ 60 L/week/1.73 m², OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: Forty-five percent of cycler patients without a daytime dwell had a mean weekly $Kt/V_{\text{urea}} \geq 2.2$ and a mean weekly creatinine clearance ≥ 66 L/week/1.73 m², OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: Fifty-eight percent of cycler patients with a daytime dwell had a mean weekly $Kt/V_{\text{urea}} \geq 2.1$ and a mean weekly creatinine clearance ≥ 63 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

Other Peritoneal Dialysis Adequacy Findings

Tidal peritoneal dialysis patients (n = 53) were excluded from the adequacy analyses reported below. By using values that were abstracted from medical records of peritoneal dialysis patients, it was possible to calculate at least one of the adequacy measures (weekly Kt/V_{urea} or weekly creatinine clearance) for 1,174 (79%) of the 1,480 patients included for these analyses during the 1999 study period.

Of the 306 (21%) medical records with insufficient information to calculate an adequacy measure, 91 (30%) had at least either one weekly Kt/V_{urea} value (86 records) or one weekly creatinine clearance value (81 records) recorded during the 1999 study period. Approximately 85% of peritoneal dialysis patients had adequacy of dialysis assessed at least once during this study period.

Fifty-six percent of CAPD and 52% of cycler patients had calculated weekly Kt/V_{urea} that met recommended

TABLE 13: Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean (\pm SD) weekly adequacy values meeting NKF DOQI guidelines, and median adequacy values, October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.

Adequacy Measure	Nov. 94–Apr. 95*		Nov. 95–Apr. 96		Nov. 96–Apr. 97		Nov. 97–Apr. 98		Oct. 98–Mar. 99	
	CAPD (n=951)	Cyclers (n=402)	CAPD (n=796)	Cyclers (n=402)	CAPD (n=757)	Cyclers (n=521)	CAPD (n=804)	Cyclers (n=663)	CAPD (n=762)	Cyclers†† (n=626)
Weekly Kt/V area										
% meeting NKF DOQI	23	28	27	28	36	36	45	42	56	52
mean (\pm SD)	1.91 (± 0.8)	2.12 (± 0.6)	2.00 (± 0.6)	2.12 (± 0.6)	2.12 (± 0.6)	2.24 (± 0.6)	2.20 (± 0.6)	2.25 (± 0.6)	2.22 (± 0.5)	2.31 (± 0.6)
median	1.90	2.00	1.90	2.00	2.00	2.20	2.10	2.20	2.20	2.30
Weekly Creatinine Clearance										
% meeting NKF DOQI	21	26	30	26	34	33	41	32	51	43
mean (\pm SD)	61.5 (± 31.6)	63.4 (± 23.5)	64.3 (± 23.6)	63.4 (± 23.5)	65.8 (± 24.7)	67.4 (± 24.4)	67.8 (± 22.6)	66.5 (± 22.0)	70.4 (± 25.2)	69.1 (± 23.7)
median	57.2	59.0	59.6	59.0	60.7	62.2	63.0	60.8	64.9	63.6

NKF DOQI guidelines:

For CAPD patients: $Kt/V_{urea} \geq 2.0$; creatinine clearance ≥ 60 L/week/1.73 m²

For cyclist patients with daytime dwell: $Kt/V_{urea} \geq 2.1$; creatinine clearance ≥ 63 L/week/1.73 m²

For nighttime cyclist patients (no daytime dwell): $Kt/V_{urea} \geq 2.2$; creatinine clearance ≥ 66 L/week/1.73 m²

*Cycler data for November 1994 – April 1995 are not shown due to low number of cyclist patients during that study period.

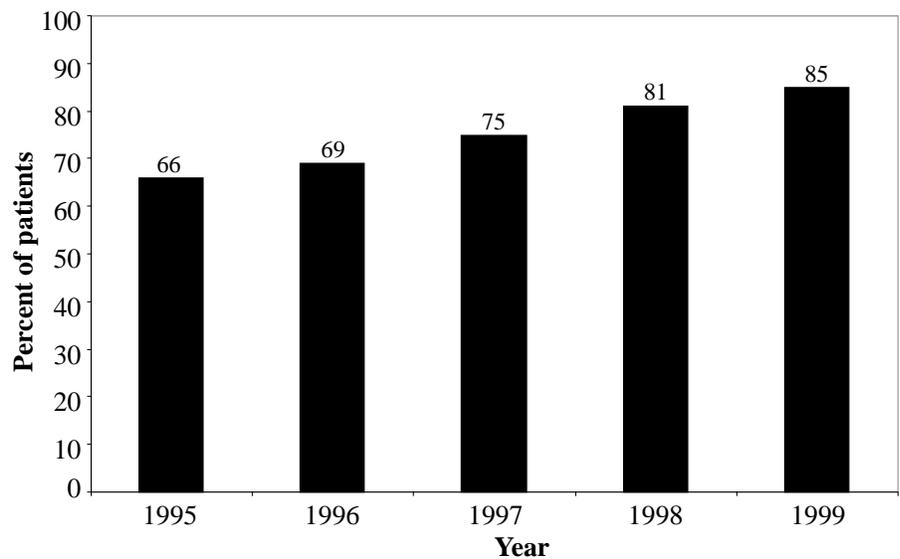
††Tidal peritoneal dialysis patients were excluded from these analyses (n=53).

NKF DOQI guidelines; 51% of CAPD and 43% of cycler patients had a mean calculated weekly creatinine clearance that met recommended NKF DOQI guidelines. (TABLE 13)

2. October 1998–March 1999 compared to previous study years

The adequacy of dialysis was assessed for approximately 85% of adult peritoneal dialysis patients at least once during the 1999 six-month study period (October 1998–March 1999), compared to only 66% during the 1995 study period, 69% during the 1996 study period, 75% during the 1997 study period, and 81% during the 1998 study period. (FIGURE 28)

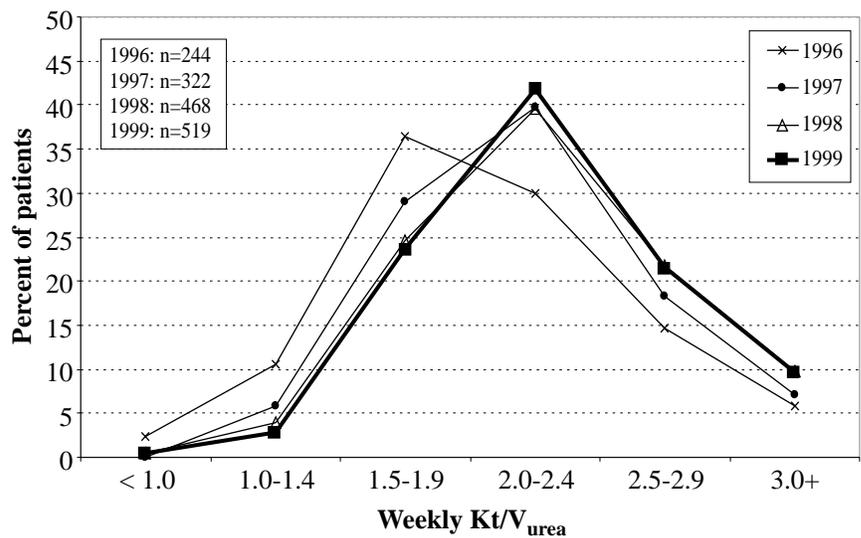
Figure 28: Estimated percent of adult (aged ≥ 18 years) peritoneal dialysis patients with at least one adequacy assessment during October 1998–March 1999, compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.



In addition to increasing numbers of patients having an adequacy measure performed during the six-month study period, both CAPD and cycler patients have experienced improved clearances from November 1994–April 1995 to October 1998–March 1999. (TABLE 13)

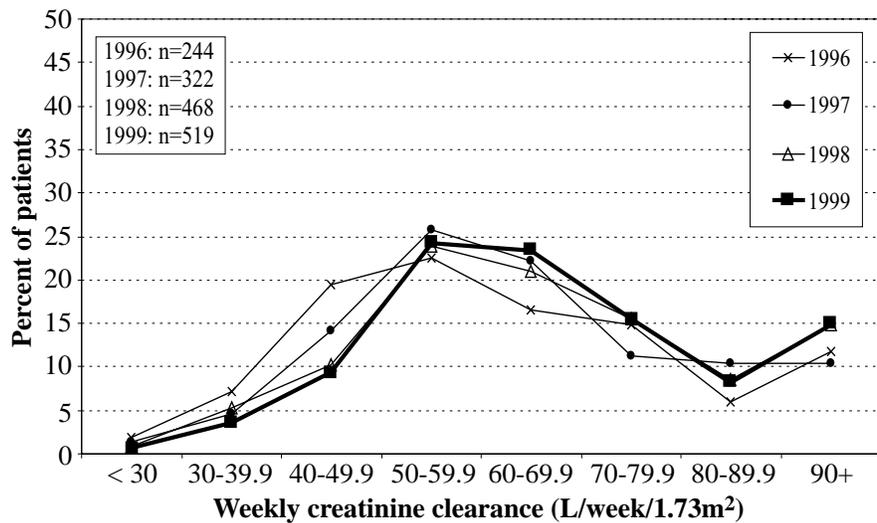
Figures 29a and 29b depict the improvement in the delivered adequacy of dialysis for cycler patients with a daytime dwell from the 1996–1999 study periods. Mean weekly Kt/V_{urea} and weekly creatinine clearance values for all cycler patients increased over this time period. (TABLE 13) A similar improvement in adequacy measures occurred for CAPD patients. (FIGURES 7a, 7b; TABLE 13)

Figure 29a: Distribution of mean weekly Kt/V_{urea} for adult (aged ≥ 18 years) cycler patients with a daytime dwell, October 1998–March 1999 compared to November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.



n = number of cycler patients with a daytime dwell

Figure 29b: Distribution of mean weekly creatinine clearance (L/week/1.73m²) for adult (aged ≥ 18 years)ycler patients with a daytime dwell, October 1998–March 1999 compared to November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.



n = number of patients with a daytime dwell in the sample

C. ANEMIA MANAGEMENT

1. October 1998–March 1999

Data to assess three anemia management CPMs were collected in 1999. The time period from which these data were abstracted was October 1998–March 1999.

Anemia Management CPM I — The target hemoglobin is 11–12 gm/dL, and the target hematocrit is 33–36%. Patients with a mean hemoglobin > 12 gm/dL or a mean hematocrit > 36% and not prescribed Epoetin were excluded from analysis for this CPM.

FINDING: For the six-month study period, 52% of the targeted peritoneal dialysis patients had a mean hemoglobin 11–12 gm/dL; 47% of patients had a mean hematocrit 33–36%.

Anemia Management CPM II a — For all anemic patients (hemoglobin < 11 gm/dL or hematocrit < 33%) or patients prescribed Epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) within three months of the first month with a first hemoglobin < 11 gm/dL or hematocrit < 33%.

FINDING: Seventy percent of the targeted peritoneal dialysis patients had at least one documented (measured) transferrin saturation value and at least one documented (measured) serum ferritin concentration value within three months of the first month with a first hemoglobin < 11 gm/dL or hematocrit < 33% during October 1998–March 1999.

Anemia Management CPM II b — For all anemic patients (hemoglobin < 11 gm/dL or hematocrit

< 33%) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation ≥ 20% were documented during the six-month study period.

FINDING: Seventy-two percent of the targeted adult peritoneal dialysis patients had at least one documented transferrin saturation ≥ 20% and at least one documented serum ferritin concentration ≥ 100 ng/mL during October 1998–March 1999.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 gm/dL or hematocrit < 33%) or patients prescribed Epoetin, with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was ≥ 50% or the mean serum ferritin concentration was ≥ 800 ng/ml; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

FINDING: Seventeen percent of the targeted peritoneal dialysis patients were prescribed intravenous iron in at least one month during October 1998–March 1999.

Other Anemia Management Findings

The average hemoglobin for these patients was 11.4 gm/dL. The average hematocrit for adult peritoneal dialysis patients in the sample was 34.5%. Overall, 52% of patients prescribed Epoetin had mean hemoglobin between 11–12 gm/dL.

The mean hemoglobin values and the proportion of patients within different hemoglobin categories

for gender, race/ethnicity, age, and diagnosis are shown in Table 14. The prevalence of severe anemia (mean hemoglobin < 9 gm/dL) was 4%. The prevalence of severe anemia was significantly higher in African-Americans compared to Caucasians and for patients 18-44 years old compared to older patients. (TABLE 14)

The average transferrin saturation for the patients in this sample was 28.2%, and 72% of patients had mean transferrin saturation \geq 20%. The average serum ferritin concentration for this population was 360 ng/mL, with 74% of patients having a mean serum ferritin concentration \geq 100 ng/mL. One hundred seventeen patients (8% of sampled patients) had both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

Because patients could have Epoetin prescribed during one month but not during another, we were not able to correlate Epoetin use with the mean hemoglobin values. Instead, we assessed Epoetin use at the time of each of the 7,615 hemoglobin determinations reported for this study period. Overall, Epoetin was prescribed 87% of the time when a hemoglobin was determined. Epoetin was prescribed 91% of the time when the hemoglobin values were < 9 gm/dL, 97% of the time when the hemoglobin values were between 9-9.9 gm/dL and between 10-10.9 gm/dL, 94% of the time when the hemoglobin values were between 11-11.9 gm/dL, and 68% of the time when hemoglobin values were 12 gm/dL.

Iron use was assessed during this study period. Iron by either the oral or intravenous route was prescribed at least once during the six months for 76% of the patients in this sample, and throughout the six-month period for 47% of the patients. Of the patients prescribed iron, 92% were prescribed oral iron and 19% were prescribed intravenous iron (not mutually exclusive categories). Among those patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 77% were prescribed either oral or IV iron at least once during the six months, and 50% received some iron all six months. Seventeen percent of these patients were prescribed IV iron at least once during the six-month study period.

TABLE 14: Mean hemoglobin values (gm/dL) for adult (aged \geq 18 years) peritoneal dialysis patients, by patient characteristics, October 1998–March 1999. 1999 ESRD CPM Project.

Patient Characteristic	Mean Hemoglobin (gm/dL)	Percent of patients with hemoglobin values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	\geq 12
TOTAL	11.4	4	9	25	31	30
GENDER						
Men	11.6	4	8	22	29	36
Women	11.2	4	10	27	34	24
RACE/ ETHNICITY						
American Indian/ Alaska Native	11.1	6	18	21	33	21
Asian/Pacific Islander	11.4	6	6	24	36	29
African-American	11.0	9	16	26	29	20
Caucasian	11.6	2	5	25	32	35
Other/Unknown	11.4	4	14	21	29	32
Hispanic	11.5	3	8	24	31	34
AGE GROUP (years)						
18-44	11.2	8	13	27	25	28
45-64	11.5	4	7	25	32	31
65+	11.5	2	8	22	36	32
DIAGNOSIS						
Diabetes Mellitus	11.4	3	8	29	30	30
Hypertension	11.3	5	11	24	29	30
Glomerulonephritis	11.3	5	10	23	35	27
Other/Unknown	11.5	6	7	21	33	33

Note: Percents may not add up to 100% due to rounding.

2. October 1998–March 1999 compared to previous study periods

The average hemoglobin increased from 11.1 gm/dL during the 1998 study period to 11.4 gm/dL during the 1999 study period. (FIGURES 6a, 30) The average hematocrit increased from 32.5% during the 1995 study period to 34.5% during the 1999 study period. (FIGURE 6b) The percentage of peritoneal dialysis patients with mean hematocrit > 30% increased from 64% to 84% over the five study periods. (FIGURE 31)

The distributions of transferrin saturation values (%) and serum ferritin concentrations (ng/mL) were similar for the November 1996–April 1997, November 1997–April 1998, and October 1998–March 1999 study periods. (FIGURES 32a, 32b)

The percent of adult (aged ≥ 18 years) peritoneal dialysis patients with severe anemia (mean hemoglobin < 9 gm/dL) decreased from 6% in the 1998 study period to 4% in the 1999 study period. (FIGURE 33)

Figure 34 depicts a trend in Epoetin dosing from the 1998 study period to the 1999 study period, with an increasing mean Epoetin dose (units/kg) for patients prescribed Epoetin in most hemoglobin categories from the 1998 to the 1999 study periods.

Figure 30: Distribution of mean hemoglobin values for adult (aged ≥ 18 years) peritoneal dialysis patients, October 1998–March 1999 compared to November 1997–April 1998. 1999 ESRD CPM Project.

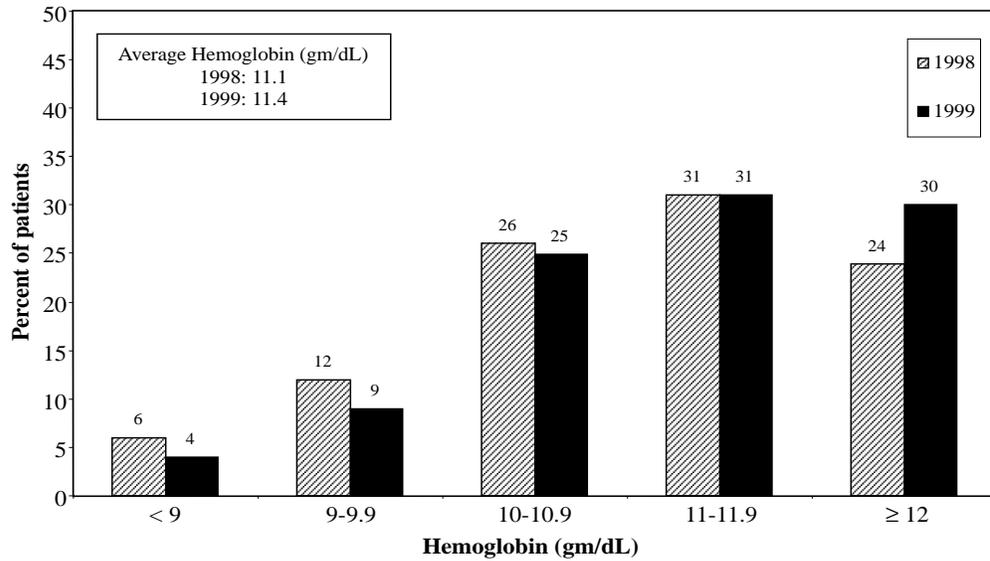


Figure 31: Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean hematocrit $> 30\%$, by race, October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.

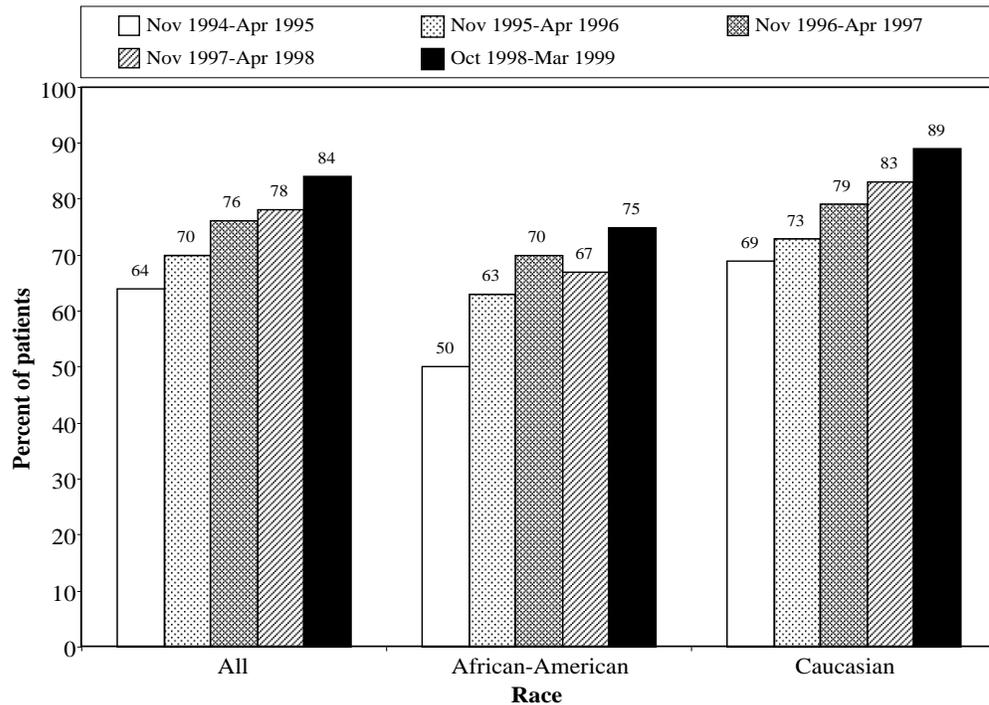


Figure 32a: Distribution of mean transferrin saturation values (%) for adult (aged ≥ 18 years) peritoneal dialysis patients, October 1998–March 1999 compared to November 1996–April 1997 and November 1997–April 1998. 1999 ESRD CPM Project.

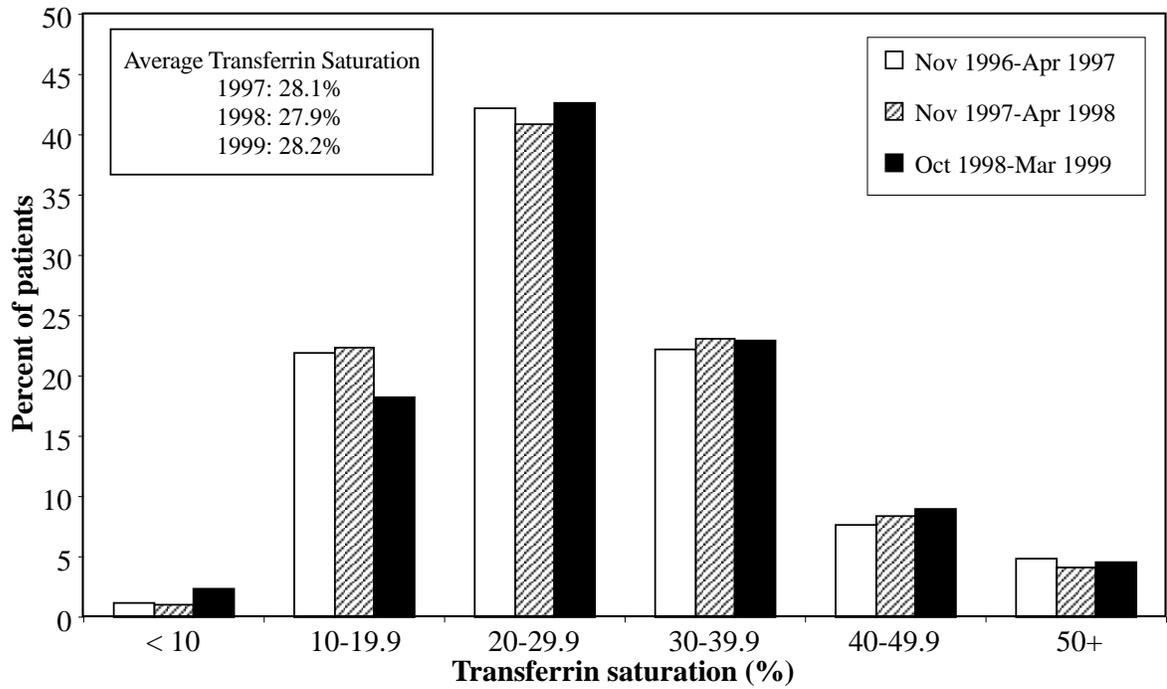


Figure 32b: Distribution of mean serum ferritin concentration (ng/mL) for adult (aged ≥ 18 years) peritoneal dialysis patients, October 1998–March 1999 compared to November 1996–April 1997 and November 1997–April 1998. 1999 ESRD CPM Project.

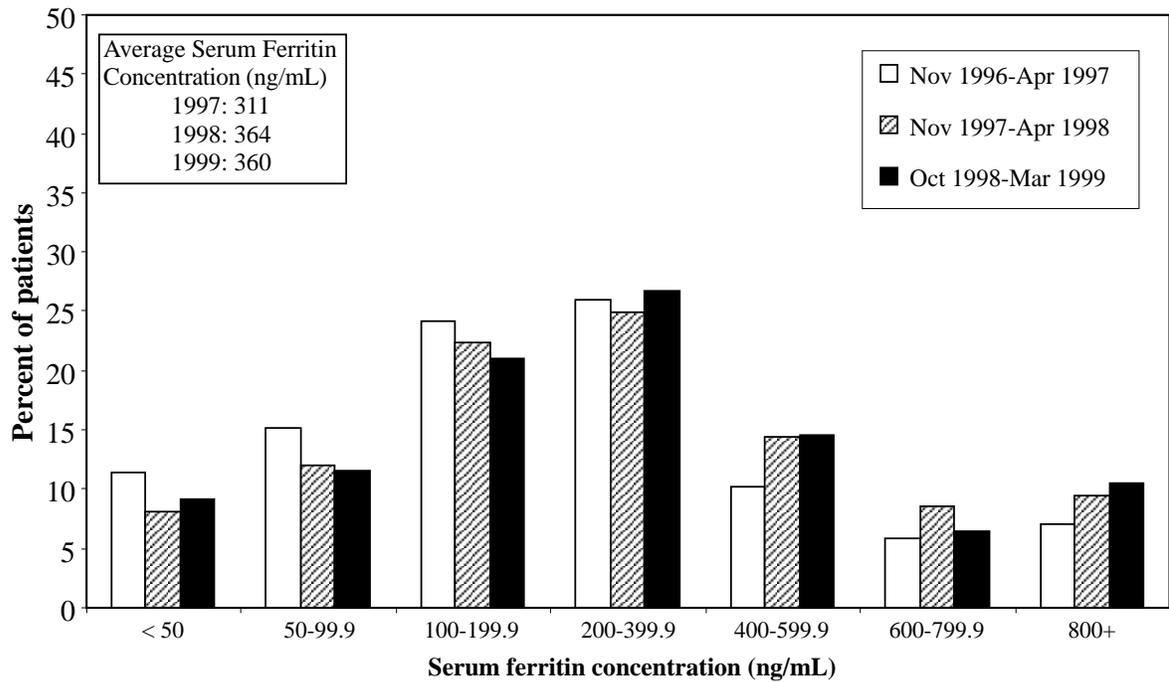


Figure 33: Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with severe anemia (mean hemoglobin < 9 gm/dL), by race, October 1998–March 1999 compared to November 1997–April 1998. 1999 ESRD CPM Project.

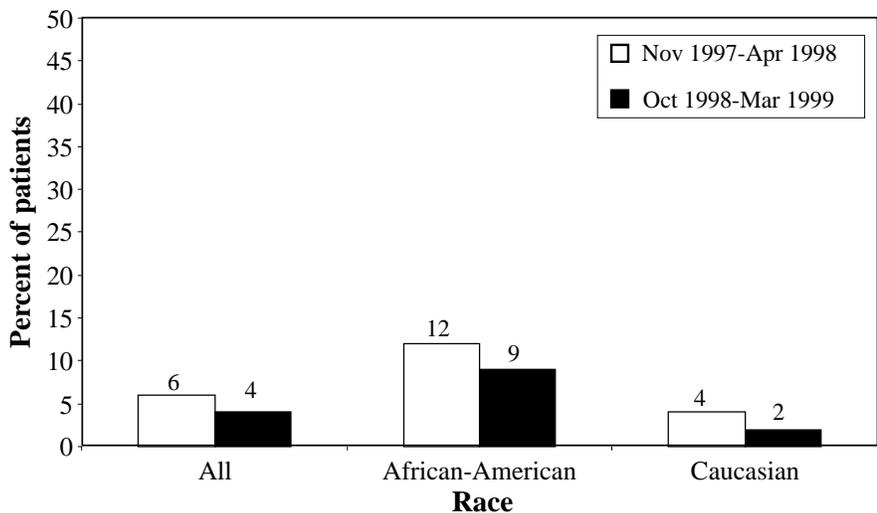
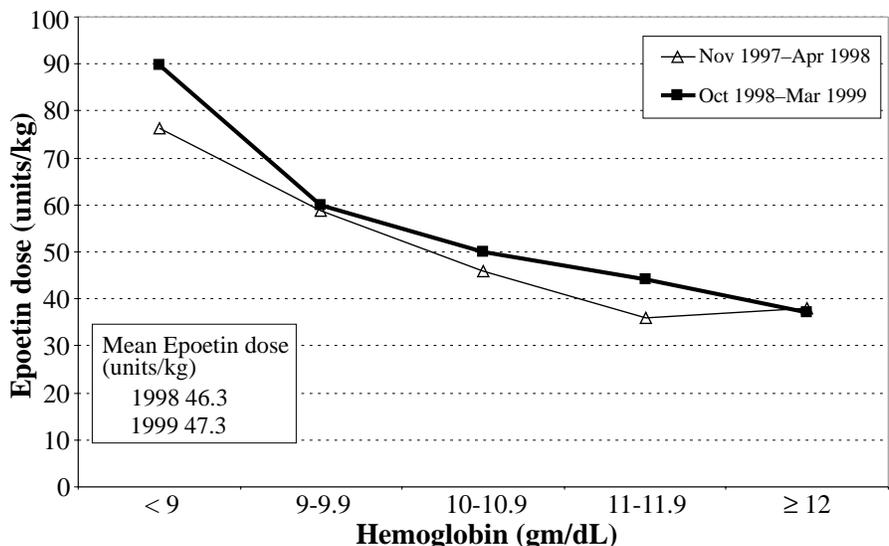


Figure 34: Mean Epoetin dose (units/kg) by hemoglobin category for adult (aged ≥ 18 years) peritoneal dialysis patients prescribed Epoetin from October 1998–March 1999 compared to November 1997–April 1998. 1999 ESRD CPM Project.



D. SERUM ALBUMIN

1. October 1998–March 1999

The mean serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method (n=1,283) was 3.5 gm/dL and by the BCP method (n=242) was 3.3 gm/dL. The mean serum albumin value by gender, race/ethnicity, age, and diagnosis and the percent of patients with mean serum albumin ≥ 3.5 gm/dL by the BCG or ≥ 3.2 gm/dL by the BCP method are shown in Table 15. The percent of patients with mean serum albumin ≥ 3.5 gm/dL by the BCG method or ≥ 3.2 gm/dL by the BCP method tended to be higher for men compared to women and for patients 18-44 years compared to older patients. (TABLE 15)

2. October 1998–March 1999 compared to previous study years

There was no clinically important change or improvement in the proportion of adult peritoneal dialysis patients with mean serum albumin ≥ 3.5 gm/dL by the BCG method or ≥ 3.2 gm/dL by the BCP method from the 1995 study period to the 1999 study period.

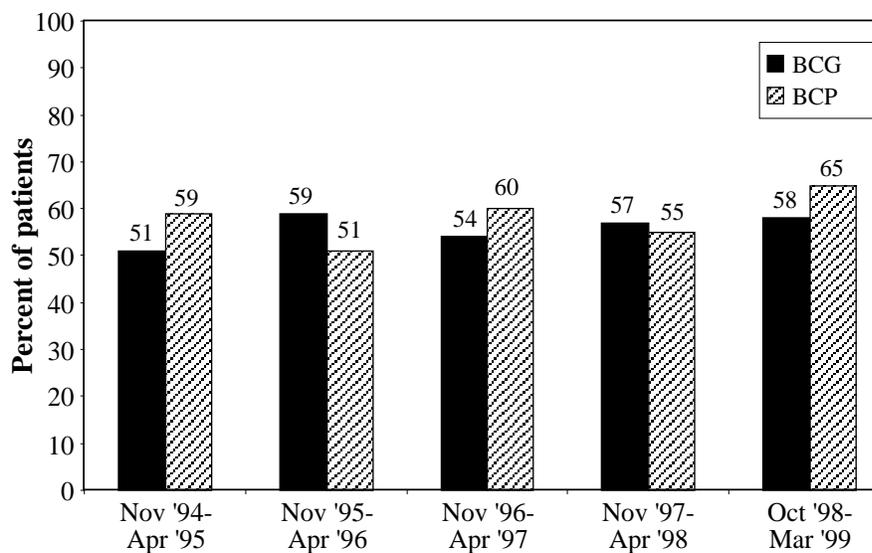
Figure 35a shows the percent of patients with mean serum albumin ≥ 3.5 gm/dL by the BCG method or ≥ 3.2 gm/dL by the BCP method during the 1999 study period compared to the 1995, 1996, 1997, and 1998 study periods. Figure 35b shows the percent of patients with mean serum albumin ≥ 4.0 gm/dL by the BCG method or ≥ 3.7 gm/dL by the BCP method during the 1999 study period, compared to the 1995, 1996, 1997, and 1998 study periods.

TABLE 15: Mean serum albumin values (gm/dL) and percent of adult (aged ≥ 18 years) peritoneal dialysis patients with serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), by patient characteristics and laboratory method*, October 1998–March 1999. 1999 ESRD CPM Project.

Patient Characteristic	BCG		BCP	
	Mean (gm/dL)	% ≥ 3.5 gm/dL	Mean (gm/dL)	% ≥ 3.2 gm/dL
TOTAL	3.5	58	3.3	65
GENDER				
Men	3.6	60	3.4	65
Women	3.5	55	3.3	65
RACE/ETHNICITY				
American Indian/Alaska Native	3.4	46	3.1	58
Asian/Pacific Islander	3.7	71	3.5	87
African-American	3.5	56	3.4	74
Caucasian	3.5	58	3.3	59
Other/Unknown	3.6	59	3.3	67
Hispanic	3.6	67	3.4	75
AGE GROUP (years)				
18–44	3.7	67	3.5	74
45–64	3.5	58	3.3	64
65+	3.4	49	3.2	55
DIAGNOSIS				
Diabetes Mellitus	3.4	47	3.2	58
Hypertension	3.6	61	3.4	69
Glomerulonephritis	3.6	66	3.4	63
Other/Unknown	3.6	62	3.4	72

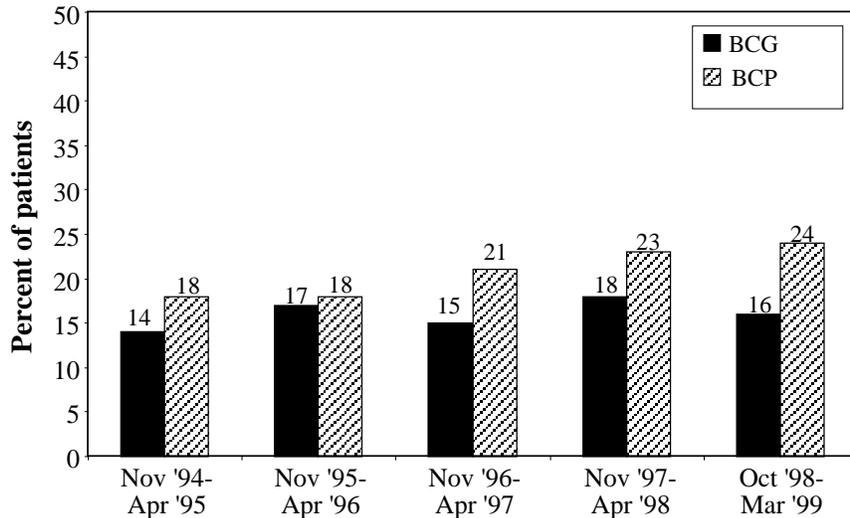
*Laboratory method: BCG = bromcresol green; BCP = bromcresol purple

Figure 35a: Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method), October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998. 1999 ESRD CPM Project.



Note: BCG = bromcresol green; BCP = bromcresol purple

Figure 35b: Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method), October 1998–March 1999 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, and November 1997–April 1998, 1999 ESRD CPM Project.



Note: BCG = bromocresol green; BCP = bromocresol purple

2000 Data Collection Effort

In 2000, we will again collect data for the ESRD Clinical Performance Measures on a national sample of adult in-center hemodialysis and adult peritoneal dialysis patients. Any questions about the Project may be addressed to your ESRD Network staff or to members of the ESRD Clinical Performance Measures Quality Improvement Workgroup. (APPENDICES 6, 7)

VIII. IMPORTANT NOTE

The data in this report are intended to stimulate the development of quality improvement (QI) projects in dialysis facilities. The data collected for this project were necessarily limited: not all dialytic parameters that influence patient care for these clinical measures were collected. In addition, the project did not attempt to develop facility-specific profiles of care.

During 2000, we plan to provide a series of supplemental reports. In these reports we will provide more detailed analysis using data collected for the ESRD CPM Project as well as other data from which we can derive information about the patients in the sample identified for this project.

As you review these data, ask yourself questions about how your patients' clinical characteristics compare to these national hemodialysis and peritoneal dialysis patient profiles and Network hemodialysis patient profiles. Additional information must be collected at your facility if you wish to answer these questions and develop ways to improve patient care for your patients. Your ESRD Network staff and Medical Review Board members are available to assist you in using these data in your QI activities and in developing facility-specific QI projects.

IX. APPENDICES

Appendix 1. ESRD Clinical Performance Measures (CPMs) Development Workgroups

Hemodialysis Adequacy Workgroup

Ralph Caruana, MD
Southeastern Kidney Council
Martinez, GA

John T. Daugirdas, MD
University of Illinois
VA Chicago Westside
Chicago, IL

Harold I. Feldman, MD, MS
University of Pennsylvania
School of Medicine
Philadelphia, PA

Diane Frankenfield, DrPH
Health Care Financing Administration
Baltimore, MD

Elizabeth Howard, RN, CNN
Gambro Healthcare
Clearwater, FL

Nathan W. Levin, MD
Renal Research Institute
New York, NY

Keith Norris, MD
King-Drew Medical Center
Los Angeles, CA

William F. Owen, Jr., MD
Brigham and Women's Hospital
Boston, MA

Susan Raulie, RN, BSN
Renal Care Group
Corpus Christi, TX

Project Staff:

Jeffrey Newman, MD, MPH (Co-Facilitator)
California Medical Review, Inc.
San Francisco, CA

Sharon Eloranta, MD (Co-Facilitator)
PRO-West
Seattle, WA

Kathryn Benedict, MA
PRO-West
Seattle, WA

Note: The affiliation of individual workgroup members may have changed since their participation in the CPM workgroup.

Appendix 1. (Continued)

Peritoneal Dialysis Adequacy Workgroup

Michael J. Flanigan, MD
University of Iowa Hospitals and Clinics
Iowa City, IA

William E. Haley, MD
Mayo Clinic
Jacksonville, FL

Kay M. Hall, BSN, RN, CNN
Health Care Financing Administration
Dallas, TX

Alan Kliger, MD
Forum of ESRD Networks
New Haven, CT

Glenda Payne, RN, MS, CNN
Texas Department of Health
Duncanville, TX

Barbara J. Prowant, MS, RN, CNN
University of Missouri-Columbia
School of Medicine
Columbia, MO

Rosa Rivera-Mizzoni, MSW
Circle Medical Management
Chicago, IL

Michael V. Rocco, MD, MS, FACP
Wake Forest University
School of Medicine
Winston-Salem, NC

Darlene J. Rodgers, BSN, RN, CNN
Intermountain ESRD Network
Denver, CO

Project Staff

W. William Schluter, MD, MSPH (Facilitator)
The Colorado Foundation for Medical Care
Aurora, CO

Steven D. Helgerson, MD, MPH
Epidemiology for Action
Seattle, WA

Laura T. Palmer, BS, CQA, MT-ASCP
The Colorado Foundation for Medical Care
Aurora, CO

Merrell Aspin
The Colorado Foundation for Medical Care
Aurora, CO

Note: The affiliation of individual workgroup members may have changed since their participation in the CPM workgroup.

Appendix 1. (Continued)

Vascular Access Workgroup

Anatole Besarab, MD, FACP
Henry Ford Hospital
Detroit, MI

Evelyn Butera, MS, RN, CNN
Satellite Dialysis Centers, Inc.
Redwood City, CA

Joel Greer, PhD
Health Care Financing Administration
Baltimore, MD

Lori James-Hartwell
Southern California Renal Disease Council
Glendale, CA

Beverly L. Ketel, MD
University of AR for Medical Sciences
Little Rock, AR

Lorabeth Lawson, MPP
Northwest Renal Network
Seattle, WA

Connie Smith, MN, RN, CNN, CPHQ
Northwest Renal Network
Seattle, WA

Charlotte Thomas-Hawkins, PhD(c), RN
University of Pennsylvania
Out-Patient Dialysis Center
Willingboro, NJ

Eli Weil, MD
Kaiser-Permanente
San Francisco, CA

Project Staff:

Renee Kanan, MD, MPH (Facilitator)
PRO-West
Seattle, WA

Earl Steinberg, MD, MPP
Covance Health Economics and Outcomes Services,
Inc.
Washington, DC

Deborah Kendall-Gallagher, RN, JD
PRO-West
Seattle, WA

Note: The affiliation of individual workgroup members may have changed since their participation in the CPM workgroup.

Appendix 1. (Continued)

Anemia Management Workgroup

M. Geraldine Biddle, RN, CNN, CPHQ
Nephrology Nurse Consultants
Loudonville, NY

Glenda Harbert, ADN, RN, CNN, CPHQ
ESRD Network of Texas, Inc.
Dallas, TX

Judith Kari, MSW, LICSW
Health Care Financing Administration
Baltimore, MD

William M. McClellan, Jr., MD, MPH
Georgia Medical Care Foundation
Atlanta, GA

Andrew S. Narva, MD
Indian Health Service
Kidney Disease Program
Albuquerque, NM

Martin S. Neff, MD
Elmhurst Hospital Center
Elmhurst, NY

Allen R. Nissenson, MD
UCLA Medical Center
Los Angeles, CA

Jacquelyn A. Polder, RN, MPH
Health Care Financing Administration
Seattle, WA

Susan A. Stark
The Renal Network, Inc.
Indianapolis, IN

Jay Wish, MD, FACP
University Hospitals of Cleveland
Cleveland, OH

Patty Wood
Kent, WA

Project Staff:

Jonathan Sugarman, MD, MPH (Facilitator)
PRO-West
Seattle, WA

Katrina Russell, RN, CNN
Dialysis Consulting Group, Inc.
Seattle, WA

Colleen Olson, MA
PRO-West
Seattle, WA

Note: The affiliation of individual workgroup members may have changed since their participation in the CPM workgroup.

Appendix 2. ESRD CPMs*

Hemodialysis Adequacy I

Clinical Performance Measure Name and Number

Hemodialysis Adequacy I: Monthly Measurement of Delivered Hemodialysis Dose

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Hemodialysis Adequacy 1: Regular Measurement of the Delivered Dose of Hemodialysis (Evidence).

The dialysis care team should routinely measure and monitor the delivered dose of hemodialysis.

Hemodialysis Adequacy 6: Frequency of Measurement of Hemodialysis Adequacy (Opinion).

The delivered dose of hemodialysis should be measured at least once a month in all adult and pediatric hemodialysis patients. The frequency of measurement of the delivered dose of hemodialysis should be increased when:

1. Patients are noncompliant with their hemodialysis prescriptions (missed treatments, late for treatments, early sign-off from hemodialysis treatments, etc.).
2. Frequent problems are noted in delivery of the prescribed dose of hemodialysis (such as variably poor blood flows, or treatment interruptions because of hypotension or angina pectoris).
3. Wide variability in urea kinetic modeling results is observed in the absence of prescription changes.
4. The hemodialysis prescription is modified.

Numerator

Numerator A: Patients in the denominator having three documented measurements of hemodialysis adequacy (urea reduction ratio [URR] and/or Kt/V) during the three-month reporting period (three measurements, one for each month, between October 1, 1998 and December 31, 1998).

Numerator B: Patients in the denominator having two documented measurements of hemodialysis adequacy (URR and/or Kt/V) during the three-month reporting period (two measurements, one in each of two months, between October 1, 1998 and December 31, 1998).

Numerator C: Patients in the denominator having one documented measurement of hemodialysis adequacy (URR and/or Kt/V) during the three-month reporting period (one measurement between October 1, 1998 and December 31, 1998).

Denominator

All hemodialysis patients ≥ 18 years old as of October 1, 1998, diagnosed with end-stage renal disease April 1, 1998 or earlier, prescribed in-center hemodialysis three times per week between October 1, 1998 and December 31, 1998, and alive as of December 31, 1998.

*The CPMs used for this report were modified slightly from previous versions for clarification and to facilitate data analysis.

Appendix 2. (Continued)

Hemodialysis Adequacy II

Clinical Performance Measure Name and Number

Hemodialysis Adequacy II: Method of Measurement of Delivered Hemodialysis Dose

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Hemodialysis Adequacy 2: Method of Measurement of Delivered Dose of Hemodialysis (Evidence).

The delivered dose of hemodialysis in adult and pediatric patients should be measured using formal urea kinetic modeling (UKM), employing the single-pool, variable volume model.

Numerator

Year One (1998): Patients in the denominator for whom each delivered hemodialysis dose recorded in the patient's chart was calculated using urea kinetic modeling (UKM), Daugirdas II, or urea reduction ratio (URR).

Year Two (1999 and beyond): Patients in the denominator for whom each delivered hemodialysis dose recorded in the patient's chart was calculated using UKM or Daugirdas II.

Denominator

All hemodialysis patients ≥ 18 years old as of October 1, 1998, diagnosed with end-stage renal disease April 1, 1998 or earlier, prescribed in-center hemodialysis three times per week between October 1, 1998 and December 31, 1998, and alive as of December 31, 1998.

Hemodialysis Adequacy III

Clinical Performance Measure Name and Number

Hemodialysis Adequacy III: Minimum Delivered Hemodialysis Dose

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Hemodialysis Adequacy 4: Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion).

The dialysis care team should deliver a Kt/V of at least 1.2 (single-pool, variable volume) for both adult and pediatric hemodialysis patients. For those using the urea reduction ratio (URR), the delivered dose should be equivalent to a Kt/V of 1.2, i.e., an average URR of 65%; however URR can vary substantially as a function of fluid removal.

Numerator

Year One (1998): Patients in the denominator whose average delivered dose of hemodialysis calculated from data points on the data collection form was either $Kt/V \geq 1.2$ or urea reduction ratio (URR) $\geq 65\%$.

Year Two (1999 and beyond): Patients in the denominator whose average delivered dose of hemodialysis calculated from data points on the data collection form was $Kt/V \geq 1.2$.

Denominator

All hemodialysis patients ≥ 18 years old as of October 1, 1998, diagnosed with end-stage renal disease April 1, 1998 or earlier, prescribed in-center hemodialysis three times per week between October 1, 1998 and December 31, 1998, and alive as of December 31, 1998.

Appendix 2. (Continued)

Hemodialysis Adequacy IV

Clinical Performance Measure Name and Number

Hemodialysis Adequacy IV: Method of Post-Dialysis Blood Urea Nitrogen (BUN) Sampling

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Hemodialysis Adequacy 8: Acceptable Methods for Blood Urea Nitrogen (BUN) Sampling (Evidence).

Blood samples for BUN measurement must be drawn in a particular manner. Pre-dialysis BUN samples should be drawn immediately prior to dialysis, using a technique that avoids dilution of the blood sample with saline or heparin. Post-dialysis BUN samples should be drawn using the Slow Flow/Stop Pump Technique that prevents sample dilution with recirculated blood and minimizes the confounding effects of urea rebound.

Numerator

Numerator A: Facilities in the denominator with written policies as of October 1, 1998 requiring post-dialysis blood urea nitrogen (BUN) sampling to be done using the slow-flow/stop-pump technique (15-60 seconds after slowing or stopping blood flow).

Numerators B - G: Facilities in the denominator with written policies as of October 1, 1998 requiring post-dialysis BUN sampling to be done: immediately without slowing/stopping blood flow; immediately after slowing/stopping blood flow; 1-2 minutes after slowing/stopping blood flow; between 2 and 15 minutes after slowing/stopping blood flow; 15 minutes or more after slowing/stopping blood flow; or no policy regarding post-dialysis BUN sampling.

NOTE: Numerators B - G are optional and supply additional information.

Denominator

All facilities included in the sample.

Hemodialysis Adequacy V

Clinical Performance Measure Name and Number

Hemodialysis Adequacy V: Baseline Total Cell Volume Measurement of Dialyzers Intended for Reuse

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Hemodialysis Adequacy 11: Baseline Measurement of Total Cell Volume (Evidence).

If a hollow-fiber dialyzer is to be reused, the total cell volume (TCV) of that hemodialyzer should be measured prior to its first use. Batch testing and/or use of an average TCV for a group of hemodialyzers is not an acceptable practice.

Numerator

Numerator A: Facilities in the denominator that, during the three-month reporting period, October 1, 1998 through December 31, 1998, pre-primed 100% of dialyzers intended for reuse.

Numerator B: Facilities in the denominator that, during the three-month reporting period, October 1, 1998 through December 31, 1998, used the manufacturer's product information to infer total cell volume (TCV).

Numerator C: Facilities in the denominator that, during the three-month reporting period, October 1, 1998 through December 31, 1998, did not preprime any dialyzers intended for reuse.

Numerator D: (which may have subsets) Facilities in the denominator that, during the three-month reporting period, October 1, 1998 through December 31, 1998, preprimed a percentage greater than zero and less than 100 percent of dialyzers intended for reuse.

Numerator E: Facilities in the denominator that, during the three-month reporting period, October 1, 1998 through December 31, 1998, inferred TCV for dialyzers intended for reuse by batch testing and/or use of an average TCV for a group of hemodialyzers.

NOTE: Numerators B - E are optional and provide additional information.

Denominator

All facilities in the sample that reuse dialyzers.

Appendix 2. (Continued)

Peritoneal Dialysis Adequacy I

Clinical Performance Measure Name and Number

Peritoneal Dialysis Adequacy I: Measurement of Total Solute Clearance at Regular Intervals

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Peritoneal Dialysis Adequacy 4: Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion).

Both total weekly creatinine clearance normalized to 1.73 m² body surface area (BSA) and total weekly K_t/V_{urea} should be used to measure delivered peritoneal dialysis doses.

Peritoneal Dialysis Adequacy 11: Dialysate and Urine Collections (Opinion).

Two to three total solute removal measurements are required during the first six months of peritoneal dialysis. (See Guideline 3.) After six months, if the dialysis prescription is unchanged:

1. Perform both complete dialysate and urine collections every four months; and
2. Perform urine collections every two months until the renal weekly K_r/V_{urea} is <0.1.

Thereafter, urine collections are no longer necessary, as the residual renal function contribution to total K_t/V_{urea} becomes negligible. (See Guideline 5.)

Numerator

Patients in denominator with total solute clearance for urea and creatinine measured at least once between October 1, 1998 and March 31, 1999.

Denominator

ESRD patients \geq 18 years old as of October 1, 1998, and alive and on peritoneal dialysis on December 31, 1998.

Appendix 2. (Continued)

Peritoneal Dialysis Adequacy II

Clinical Performance Measure Name and Number

Peritoneal Dialysis Adequacy II: Calculate Weekly Kt/V_{urea} and Creatinine Clearance in a Standard Way

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Peritoneal Dialysis Adequacy 4: Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion).

Both total weekly creatinine clearance normalized to 1.73 m² body surface area (BSA) and total weekly Kt/V_{urea} should be used to measure delivered peritoneal dialysis doses.

Peritoneal Dialysis Adequacy 6: Assessing Residual Renal Function (Evidence).

Residual renal function (RRF), which can provide a significant component of total solute and water removal, should be assessed by measuring the renal component of Kt/V_{urea} (K_r/V_{urea}) and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance.

Peritoneal Dialysis Adequacy 9: Estimating Total Body Water and Body Surface Area (Opinion).

V (total body water) should be estimated by either the Watson or Hume method in adults using actual body weight.

Watson method:

For Men: V (liters) = $2.447 + 0.3362 * W_t(\text{kg}) + 0.1074 * H_t(\text{cm}) - 0.09516 * \text{Age}(\text{years})$

For Women: $V = -2.097 + 0.2466 * W_t + 0.1069 * H_t$

Hume method:

For Men: $V = -14.012934 + 0.296785 * W_t + 0.192786 * H_t$

For Women: $V = -35.270121 + 0.183809 * W_t + 0.344547 * H_t$

BSA should be estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method using actual body weight.

For all formulae, W_t is in kg and H_t is in cm:

DuBois and DuBois method: BSA (m²) = $71.84 * W_t^{0.425} * H_t^{0.725}$

Gehan and George method: BSA (m²) = $0.0235 * W_t^{0.51456} * H_t^{0.42246}$

Haycock method: BSA (m²) = $0.024265 * W_t^{0.5378} * H_t^{0.3964}$

Numerator

Patients in denominator with all of the following:

- Weekly creatinine clearance normalized to 1.73 m² body surface area (BSA) and total weekly Kt/V_{urea} used to measure delivered peritoneal dialysis dose; AND
- Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} (K_r/V_{urea}) and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance; AND
- Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight.

*negligible = < 200 cc urine in 24 hours

Denominator

ESRD patients ≥ 18 years old as of October 1, 1998, and alive and on peritoneal dialysis on December 31, 1998.

Appendix 2. (Continued)

Peritoneal Dialysis Adequacy III

Clinical Performance Measure Name and Number

Peritoneal Dialysis Adequacy III: Delivered Dose of Peritoneal Dialysis

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Peritoneal Dialysis Adequacy 15: Weekly Dose of CAPD (Evidence).

For CAPD, the delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.0 per week and a total creatinine clearance (C_{cr}) of at least 60 L/week/1.73 m².

Peritoneal Dialysis Adequacy 16: Weekly Dose of NIPD and CCPD (Opinion).

For cycler patients without a daytime dwell, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.2 and a weekly total creatinine clearance of at least 66 L/1.73 m².

For cycler patients with a daytime dwell, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.1 and a weekly total creatinine clearance of at least 63 L/1.73 m².

Numerator

Patients in denominator:

For CAPD, the delivered peritoneal dialysis dose was a weekly Kt/V_{urea} of at least 2.0 and a weekly creatinine clearance of at least 60 L/week/1.73 m², OR evidence that prescription was changed according to NKF-DOQI recommendations.

For cycler patients without a daytime dwell, the delivered peritoneal dialysis dose was a weekly Kt/V_{urea} of at least 2.2 and a weekly creatinine clearance of at least 66 L/week/1.73 m², OR evidence that prescription was changed according to NKF-DOQI recommendations.

For cycler patients with a daytime dwell, the weekly delivered peritoneal dialysis dose was a weekly Kt/V_{urea} of at least 2.1 and a weekly creatinine clearance of at least 63 L/week/1.73 m², OR evidence that prescription was changed according to NKF-DOQI recommendations.

Denominator

ESRD patients \geq 18 years old as of October 1, 1998, and alive and on peritoneal dialysis on December 31, 1998.

Appendix 2. (Continued)

Vascular Access I

Clinical Performance Measure Name and Number

Vascular Access I: Maximizing Placement of Arterial Venous Fistulae (AVF)

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Vascular Access 29A: Goals of Access Placement-Maximizing Primary Arterial Venous Fistulae (Opinion).

Primary arterial venous fistulae (AVF) should be constructed in at least 50% of all new patients electing to receive hemodialysis as their initial form of renal replacement therapy. Ultimately, 40% of prevalent patients should have a native AV fistula. (See Guideline 3, Selection of Permanent Vascular Access and Order of Preference of AV Fistulae.)

Numerator

Numerator A: Incident patients in the denominator who were dialyzed using an arterial venous fistula (AVF) during their last hemodialysis treatment on or between October 1, 1998 and December 31, 1998.

Numerator B: Prevalent patients in the denominator who were dialyzed using an AVF during their last hemodialysis treatment on or between October 1, 1998 and December 31, 1998.

Denominator

Denominator A: Incident ESRD patients ≥ 18 years old as of October 1, 1998, who initiated their most recent maintenance course of hemodialysis for end-stage renal disease on or between January 1, 1998 and August 31, 1998, who were alive on December 31, 1998, and who were on hemodialysis continuously between October 1, 1998 and December 31, 1998, inclusive.

Denominator B: Prevalent ESRD patients ≥ 18 years old as of October 1, 1998, who were alive on December 31, 1998 and who were on hemodialysis continuously between October 1, 1998 and December 31, 1998, inclusive. Prevalent patients include patients incident between January 1, 1998 and August 31, 1998.

Vascular Access II

Clinical Performance Measure Name and Number

Vascular Access II: Minimizing Use of Catheters as Chronic Dialysis Access

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Vascular Access 30A: Goals of Access Placement- Use of Catheters for Chronic Dialysis (Opinion).

Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than three months in the absence of a maturing permanent access.

Numerator

Patients in the denominator who were dialyzed with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session on or between October 1, 1998 and December 31, 1998.

Denominator

Patients ≥ 18 years old as of October 1, 1998, who were alive on December 31, 1998, who were on hemodialysis continuously between October 1, 1998 and December 31, 1998, inclusive, and who received their last hemodialysis session on or between October 1, 1998 and December 31, 1998.

Appendix 2. (Continued)

Vascular Access III

Clinical Performance Measure Name and Number

Vascular Access III: Preferred/Non-Preferred Location of Hemodialysis Catheters Located above the Waist

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Vascular Access 5B: Type and Location of Tunneled Cuffed Catheter Placement (Evidence).

The preferred insertion site for tunneled cuffed venous dialysis catheters is the right internal jugular vein. Other options include: the right external jugular vein, the left internal and external jugular veins, subclavian veins, femoral veins, or translumbar access to the inferior vena cava. Subclavian access should be used only when jugular options are not available. Tunneled cuffed catheters should not be placed on the same side as a maturing arterial venous access, if possible.

Vascular Access 6D: Acute Hemodialysis Vascular Access-Noncuffed Catheters (Evidence).

The subclavian insertion site should not be used in a patient who may need permanent vascular access.

Numerator

Numerator A: Patients in the denominator who used a jugular vein catheter as dialysis access at their last hemodialysis session on or between October 1, 1998 and December 31, 1998.

Numerator B: Patients in the denominator who used a subclavian vein catheter as dialysis access at their last hemodialysis session on or between October 1, 1998 and December 31, 1998.

Denominator

Patients \geq 18 years old as of October 1, 1998, who were alive on December 31, 1998, who were on hemodialysis continuously between October 1, 1998 and December 31, 1998, inclusive, and who were dialyzed through a catheter during their last hemodialysis treatment on or between October 1, 1998 and December 31, 1998.

Appendix 2. (Continued)

Vascular Access IV

Clinical Performance Measure Name and Number

Vascular Access IV: Monitoring Arterial Venous Grafts for Stenosis

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Vascular Access 10: Monitoring Dialysis AV Grafts for Stenosis (Evidence/Opinion).

Physical examination of an access graft should be performed weekly and should include, but not be limited to, inspection and palpation for pulse and thrill at the arterial, mid, and venous sections of the graft (Opinion). Dialysis arterial venous graft accesses should be monitored for hemodynamically significant stenosis. The NKF DOQI Work Group recommends an organized monitoring approach with regular assessment of clinical parameters of the arterial venous access and dialysis adequacy. Data from the monitoring tests, clinical assessment, and dialysis adequacy measurements should be collected and maintained for each patient's access and made available to all staff. The data should be tabulated and tracked within each dialysis center as part of a Quality Assurance/ Continuous Quality Improvement (QA/CQI) program (Opinion). Prospective monitoring of arterial venous grafts for hemodynamically significant stenosis, when combined with correction, improves patency and decreases the incidence of thrombosis (Evidence). Techniques, not mutually exclusive, that can be used to monitor for stenosis in arterial venous grafts include:

- A. Intra-access flow (Evidence)
 - B. Static venous pressures (Evidence)
 - C. Dynamic venous pressures (Evidence)
- Other studies or information that can be useful in detecting arterial venous graft stenosis include:
- D. Measurement of access recirculation using urea concentrations (See Guideline 12.) (Evidence)
 - E. Measurement of recirculation using dilution techniques (nonurea-based) (Evidence)
 - F. Unexplained decreases in the measured amount of hemodialysis delivered (URR, Kt/V) (Evidence)
 - G. Physical findings of persistent swelling of the arm, clotting of the graft, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in a graft (Evidence/Opinion)
 - H. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow (Evidence/Opinion)
 - I. Doppler ultrasound (Evidence/Opinion)

Persistent abnormalities in any of these parameters should prompt referral for venography (Evidence).

Numerator

Patients in the denominator whose AV graft was routinely monitored (screened) for the presence of stenosis on or between October 1, 1998 and December 31, 1998 by one of the following methods and with the stated frequency:

- Color-flow Doppler at least once every 3 months
- Static venous pressure at least once every 2 weeks
- Dynamic venous pressure every HD session
- Dilution technique at least once every 3 months

Denominator

Patients ≥ 18 years old as of October 1, 1998, who were alive on December 31, 1998, who were on hemodialysis continuously between October 1, 1998 and December 31, 1998, inclusive, and who were dialyzed through an arterial venous graft during their last hemodialysis session occurring on or between October 1, 1998 and December 31, 1998.

Appendix 2. (Continued)

Anemia Management I

Clinical Performance Measure Name and Number

Anemia Management I: Target Hematocrit for Epoetin Therapy

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Anemia Management 4: Target Hemoglobin/Hematocrit for Epoetin Therapy (Evidence/Opinion).

The target range for hemoglobin should be 11–12 gm/dL and the target range for hematocrit should be 33%-36%. This target is for Epoetin therapy and is not for blood transfusion therapy (Opinion).

Numerator

Numerator A₁: Patients in the denominator with mean hemoglobin 11-12 gm/dL. Mean hemoglobin to be calculated as arithmetic mean of first listed hemoglobin of the month for each of the three months in the surveillance period.

Numerator A₂: Patients in the denominator with mean hematocrit 33%-36%. Mean hematocrit to be calculated as arithmetic mean of first listed hematocrit of the month for each of the three months in the surveillance period.

Numerator B₁: Patients in the denominator with mean hemoglobin 11-12 gm/dL. Mean hemoglobin to be calculated as arithmetic mean of first listed hemoglobin of the month for each of the six months in the surveillance period.

Numerator B₂: Patients in the denominator with mean hematocrit 33%-36%. Mean hematocrit to be calculated as arithmetic mean of first listed hematocrit of the month for each of the six months in the surveillance period.

Denominator

Denominator A: In-center hemodialysis patients, ≥ 18 years old as of October 1, 1998, on hemodialysis from October 1, 1998 through December 31, 1998, and alive on December 31, 1998.

EXCLUDE patients with mean hemoglobin > 12 gm/dL (hematocrit > 36%) who are NOT prescribed Epoetin at any time during the three-month surveillance period. (Mean hemoglobin/hematocrit levels are calculated as the arithmetic mean of the first listed hemoglobin/hematocrit for each month in the surveillance period.)

Denominator B: Peritoneal dialysis patients, ≥ 18 years old as of October 1, 1998, and alive and on peritoneal dialysis on December 31, 1998.

EXCLUDE patients with mean hemoglobin > 12 gm/dL (hematocrit > 36%) who are NOT prescribed Epoetin at any time during the six-month surveillance period. (Mean hemoglobin/hematocrit levels are calculated as the arithmetic mean of the first listed hemoglobin/hematocrit for each month in the surveillance period.)

Appendix 2. (Continued)

Anemia Management IIa

Clinical Performance Measure Name and Number

Anemia Management IIa: Assessment of Iron Stores among Anemic Patients or Patients Prescribed Epoetin

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Anemia Management 5: Assessment of Iron Status (Evidence).

Iron status should be monitored by the percent transferrin saturation and the serum ferritin concentration.

Anemia Management 6A: Target Iron Level (Evidence).

Chronic renal failure patients should have sufficient iron to achieve and maintain a hemoglobin (hematocrit) of 11 to 12 gm/dL (33% to 36%).

Anemia Management 7A: Monitoring Iron Status (Opinion).

During the initiation of Epoetin therapy and while increasing the Epoetin dose in order to achieve an increase in hemoglobin/hematocrit, the transferrin saturation and the serum ferritin concentration should be checked every month in patients not receiving intravenous iron, and at least once every 3 months in patients receiving intravenous iron, until target hemoglobin/hematocrit is reached.

Anemia Management 7B: Monitoring Iron Status (Opinion).

Following attainment of the target hemoglobin/hematocrit, transferrin saturation and serum ferritin concentration should be determined at least once every 3 months.

Numerator

Numerator A: Patients in the denominator with at least one documented transferrin saturation result and at least one documented serum ferritin concentration result during the three month review period.

Numerator B: Patients in the denominator with at least one documented transferrin saturation result and at least one documented serum ferritin concentration result within three months of the first month with a first hemoglobin < 11 gm/dL or hematocrit < 33%.

Denominator

Denominator A: In-center hemodialysis patients, ≥ 18 years old as of October 1, 1998, on hemodialysis from October 1, 1998 through December 31, 1998, and alive on December 31, 1998, if first monthly hemoglobin < 11 gm/dL or hematocrit < 33% for at least one of the three study months or if prescribed Epoetin at any time between October 1, 1998 and December 31, 1998, regardless of hemoglobin.

Denominator B: Peritoneal dialysis patients, ≥ 18 years old as of October 1, 1998, and alive and on peritoneal dialysis on December 31, 1998, if first monthly hemoglobin < 11 gm/dL or hematocrit < 33% for at least one of the six study months or if prescribed Epoetin, regardless of hemoglobin.

Appendix 2. (Continued)

Anemia Management IIb

Clinical Performance Measure Name and Number

Anemia Management IIb: Maintenance of Iron Stores-Target

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Anemia Management 6B: Target Iron Level (Evidence).

To achieve and maintain this target hemoglobin/hematocrit, sufficient iron should be administered to maintain a transferrin saturation $\geq 20\%$, and a serum ferritin concentration ≥ 100 ng/mL.

Numerator

Numerator A: Patients in the denominator with at least one documented transferrin saturation $\geq 20\%$ and at least one documented serum ferritin concentration ≥ 100 ng/mL during the three month period.

Numerator B: Patients in the denominator with at least one documented transferrin saturation $\geq 20\%$ and at least one documented serum ferritin concentration ≥ 100 ng/mL during the six month period. [Note: Not directly comparable to Numerator A, but most feasible given probable frequency of visits for peritoneal dialysis patients.]

Denominator

Denominator A: In-center hemodialysis patients, ≥ 18 years old as of October 1, 1998, on hemodialysis from October 1, 1998 through December 31, 1998, and alive on December 31, 1998, if first monthly hemoglobin < 11 gm/dL or hematocrit $< 33\%$ for at least one of the three study months or if prescribed Epoetin, regardless of hemoglobin.

Denominator B: Peritoneal dialysis patients, ≥ 18 years old as of October 1, 1998, and alive and on peritoneal dialysis on December 31, 1998, if first monthly hemoglobin < 11 gm/dL or hematocrit $< 33\%$ for at least one of the six study months or if prescribed Epoetin, regardless of hemoglobin.

Appendix 2. (Continued)

Anemia Management III

Clinical Performance Measure Name and Number

Anemia Management III: Administration of Supplemental Iron

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

Anemia Management 8A: Administration of Supplemental Iron (Evidence).

Supplemental iron should be administered to prevent iron deficiency and to maintain adequate iron stores so that chronic renal failure patients can achieve and maintain a hemoglobin 11 to 12 gm/dL (hematocrit 33% to 36%) in conjunction with Epoetin therapy.

Anemia Management 8C: Administration of Supplemental Iron (Evidence/Opinion).

The adult pre-dialysis, home hemodialysis, and peritoneal dialysis patient may not be able to maintain adequate iron status with oral iron. Therefore, 500 to 1000 mg of iron dextran may be administered intravenously in a single infusion, and repeated as needed, after an initial one-time test dose of 25 mg.

Anemia Management 8D: Administration of Supplemental Iron (Opinion/Evidence).

A trial of oral iron is acceptable in the hemodialysis patient, but is unlikely to maintain the transferrin saturation $\geq 20\%$, serum ferritin concentration ≥ 100 ng/mL, and hemoglobin /hematocrit at 11-12 gm/dL /33%-36%.

Anemia Management 8G: Administration of Supplemental Iron (Opinion/Evidence).

Most patients will achieve a hemoglobin 11 to 12 gm/dL (hematocrit 33% to 36%) with transferrin saturation and serum ferritin concentration $< 50\%$ and < 800 ng/mL, respectively. In patients in whom transferrin saturation is $\geq 50\%$ and/or serum ferritin concentration is ≥ 800 ng/mL, intravenous iron should be withheld for up to three months, at which time the iron parameters should be re-measured before intravenous iron is resumed. When the transferrin saturation and serum ferritin concentration have fallen to $\leq 50\%$ and ≤ 800 ng/mL, intravenous iron can be resumed at a dose reduced by one-third to one-half.

Anemia Management 8H: Administration of Supplemental Iron (Opinion).

It is anticipated that once optimal hemoglobin/hematocrit and iron stores are achieved, the required maintenance dose of intravenous iron may vary from 25 to 100 mg/week for hemodialysis patients. The goal is to provide a weekly dose of intravenous iron in hemodialysis patients that will allow the patient to maintain the target hemoglobin/hematocrit at a safe and stable iron level. The maintenance iron status should be monitored by measuring the transferrin saturation and serum ferritin concentration every three months.

Numerator

Numerators A and B: Number of patients in denominator prescribed intravenous iron in at least one month.

Denominator

Denominator A: In-center hemodialysis patients, ≥ 18 years old as of October 1, 1998, on hemodialysis from October 1, 1998 through December 31, 1998, and alive on December 31, 1998, if first monthly hemoglobin < 11 gm/dL or hematocrit $< 33\%$ for at least one of the three study months or if prescribed Epoetin, regardless of hemoglobin, with at least one transferrin saturation $< 20\%$ or at least one serum ferritin concentration < 100 ng/mL.

EXCLUDE patients with a mean transferrin saturation $\geq 50\%$ OR a mean serum ferritin concentration ≥ 800 ng/mL AND

EXCLUDE patients in first three months of dialysis AND prescribed oral iron.

Denominator B: Peritoneal dialysis patients, ≥ 18 years old as of October 1, 1998, alive, and on peritoneal dialysis on December 31, 1998, if first monthly hemoglobin < 11 gm/dL or hematocrit $< 33\%$ for at least one of the six study months or if prescribed Epoetin, regardless of hemoglobin, with at least one transferrin saturation $< 20\%$ or at least one serum ferritin concentration < 100 ng/mL.

EXCLUDE patients with a mean transferrin saturation $\geq 50\%$ OR a mean serum ferritin concentration ≥ 800 ng/mL AND

EXCLUDE patients in first three months of dialysis AND prescribed oral iron.

Appendix 3. 1999 CPM Data Collection Form — In-Center Hemodialysis

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: 1999

[Before completing please read instructions at the bottom of this page and on pages 3 and 4]

PATIENT IDENTIFICATION	MAKE CORRECTIONS TO PATIENT INFORMATION ON LEFT IN THE SPACE BELOW
PLACE PATIENT DATA LABEL HERE	
	10a. Is Patient Hispanic? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
11. If the above patient information is incorrect make corrections in space above then continue to question 12. Please verify patient's race and check question 10a. above. If patient unknown or was not dialyzed in the unit at any time during OCT 1998 – DEC 1998 return the form to the Network.	
12. Patient's height (MUST COMPLETE): _____ inches _____ centimeters	
13. Does patient have limb amputation(s): <input type="checkbox"/> Yes <input type="checkbox"/> No	
14. The most RECENT date this patient initiated (or re-initiated) dialysis was: ____/____/____. [NOTE: This date may be different than the date this patient FIRST initiated dialysis; item 8 above]	
PLEASE COMPLETE ITEMS 15, 16 AND 17 ON PAGE 2 OF THIS DATA COLLECTION FORM AND ITEMS 18 ON PAGE 3.	
Individual Completing Form (Please print): First name: _____ Last name: _____ Title: _____ Phone number: (____) _____ - _____ Fax number: (____) _____ - _____	

INSTRUCTIONS FOR COMPLETING THE IN-CENTER HEMODIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: 1999

The label on the top left side of this form (#'s 1-8) contains the following patient identifying information. If the information is incorrect make corrections to the right of the label.

- | | |
|---|---|
| 1. LAST and first name.
3. SOCIAL Security Number (SSN).
5. SEX (M=Male; F=Female; U=Unknown).
7. PRIMARY cause of renal failure by HCFA-2728 code.
9. ESRD Network number. Do not make corrections to this item. | 2. DATE of birth (DOB) as MM/DD/YYYY.
4. HEALTH Insurance Claim Number (HIC).
6. RACE (0=Unknown; 1=White; 2=Black; 3=Other; 4=Asian/Pacific Islander; 6=American Indian/Alaska Native).
8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.

10. Facility's Medicare provider number.
10a. Is the patient Hispanic? Check either Yes, No, or Unknown, as appropriate. |
|---|---|
11. Review the patient and facility specific information contained on the pre-printed label. Please verify the patient's race, item 6 above. If any of the information is incorrect write corrections in the space to the right of the label. If the patient is unknown or if the patient was not dialyzed in the unit at any time during OCT 1998 through DEC 1998, send the form back to the ESRD Network office with the name and address of the facility providing services to this patient on December 31, 1998, if known.
 12. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank, you may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height and check YES for item 13.
 13. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but check YES if this Patient has had a below-knee, below-elbow, or more proximal (extensive) amputation.
 14. Enter the most recent date this patient initiated (or re-initiated) any form of dialysis. This date may be different than the date this patient first initiated dialysis (item 8), e.g., the patient may have re-initiated hemodialysis after a failed transplantation.

PLEASE COMPLETE ITEMS 15, 16, AND 17 ON PAGE 2 OF THIS DATA COLLECTION FORM AND ITEM 18 ON PAGE 3.
 INSTRUCTIONS FOR COMPLETING THESE ITEMS ARE ON PAGES 3 AND 4.

Appendix 3. (Continued)

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)			
15. SERUM ALBUMIN: Enter the FIRST monthly serum albumin FOR EACH MONTH: OCT, NOV, DEC 1998 . Check the method used by lab to determine the serum albumins. If method unknown, please call lab to find out. Do not leave blank.			
	OCT 1998	NOV 1998	DEC 1998
A. First monthly serum albumin:	_____ . _____ gm/dL	_____ . _____ gm/dL	_____ . _____ gm/dL
B. Check lab method used (BCG = bromcresol green; BCP = bromcresol purple)	<input type="checkbox"/> BCGreen <input type="checkbox"/> BCPurple	<input type="checkbox"/> BCGreen <input type="checkbox"/> BCPurple	<input type="checkbox"/> BCGreen <input type="checkbox"/> BCPurple
LAB DATA. The following data are requested for OCT, NOV, & DEC 1998. For each question, use the FIRST LAB VALUES OF THE MONTH . Do not leave any questions blank. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: NF if Not Found. HOSP if patient was hospitalized during the month. TRANS if patient was absent during the month.			
16. HEMATOCRIT: Enter the FIRST Hematocrit (HCT) and Hemoglobin (HGB) determined by Lab's Coulter Counter or other hematology instrument for EACH MONTH OCT, NOV, DEC 1998 . Record both HGB and HCT only if both were drawn on the same date. DO NOT ENTER SPUN HCT VALUE, unless your facility does not obtain lab HCTs . Also enter the prescribed WEEKLY EPO dose and the route of administration; the first monthly Ferritin and Transferrin Saturation value and the route of iron administration .			
	OCT 1998	NOV 1998	DEC 1998
A. First monthly pre-dialysis laboratory hematocrit:	_____ . _____ %	_____ . _____ %	_____ . _____ %
B. First monthly pre-dialysis laboratory hemoglobin:	_____ . _____ g/dL	_____ . _____ g/dL	_____ . _____ g/dL
C. What was the PRESCRIBED WEEKLY EPO dose at the time immediately BEFORE the above HCT/HGB were drawn?	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription
D. What was the prescribed route of EPO administration related to item 16C?	_____ IV _____ SC	_____ IV _____ SC	_____ IV _____ SC
E. First monthly Ferritin value:	_____ ng/mL	_____ ng/mL	_____ ng/mL
F. First monthly Transferrin Saturation value:	_____ %	_____ %	_____ %
G. Was iron prescribed at any time during the month?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No
H. If yes, what was the route of administration? (check all that apply)	_____ IV _____ P.O.	_____ IV _____ P.O.	_____ IV _____ P.O.
17. ADEQUACY: Enter the first monthly pre- and post-dialysis BUN FOR EACH MONTH: OCT, NOV, DEC 1998 . The pre- and post-dialysis BUNs must be drawn on the same day of the month. If only performed quarterly, enter the FIRST values for the month performed and enter "NP" for the other two months. Also, enter the patient's actual DELIVERED time on dialysis when the BUNs were drawn and the CODE for the name of the dialyzer used at the time the BUNs were drawn. (see attached chart for the dialyzer codes.)			
	OCT 1998	NOV 1998	DEC 1998
A. How many times per week was this patient scheduled to receive dialysis?	_____ times per week	_____ times per week	_____ times per week
B. First monthly Pre-dialysis BUN:	_____ mg/dL	_____ mg/dL	_____ mg/dL
C. First monthly Post-dialysis BUN:	_____ mg/dL	_____ mg/dL	_____ mg/dL
D. Patient's PRE- & POST-dialysis weight when above BUNs were drawn: (Circle either lbs or kgs)	Pre: _____ lbs / kgs Post: _____ lbs / kgs	Pre: _____ lbs / kgs Post: _____ lbs / kgs	Pre: _____ lbs / kgs Post: _____ lbs / kgs
E. Actual DELIVERED time on dialysis at session when BUNs drawn:	_____ hrs _____ min	_____ hrs _____ min	_____ hrs _____ min
F. Delivered blood flow rate @60 min. during session at which BUNs are drawn.	_____ ml/min	_____ ml/min	_____ ml/min
G. Code for dialyzer used on dialysis at session when BUNs drawn: (see chart)	_____	_____	_____
H. First monthly recorded URR	_____ %	_____ %	_____ %
I. First monthly recorded Kt/V (If both URR and Kt/V were recorded, answer both 17H & 17I)	_____ Kt/V	_____ Kt/V	_____ Kt/V
J. Method used to calculate Kt/V	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown

Appendix 3. (Continued)

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)	
18. VASCULAR ACCESS: Please reconfirm date patient began a regular course of dialysis (item 8, above). If the correct date for item 8 is January 1, 1998 or after, answer questions 18A through 18F₂. If the correct date for item 8 is prior to January 1, 1998, answer only items 18D through 18F₂.	
A. What type of access was in use at the initiation of <u>first time</u> hemodialysis? (regardless of setting)	<input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown
B. When was the access in item 18A placed ?	____/____/____ <input type="checkbox"/> Unknown
C. What type of access was used 90 days after the initiation of hemodialysis? (regardless of setting)	<input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown
NOTE: If answer to 18D is "Catheter," complete questions 18E₁ and 18E₂. If the answer to 18D is "Synthetic Graft" or "Bovine Graft," complete questions 18F₁ and 18F₂. If the answer to 18D is "AV Fistula," "Other," or "Unknown," you are done with the questionnaire.	
D. What type of access was used on the last hemodialysis session on or between 10/1/98 and 12/31/98 at the patient's primary in-center facility?	<input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown
E ₁ . What was the insertion location of the catheter?	<input type="checkbox"/> Subclavian <input type="checkbox"/> Femoral <input type="checkbox"/> Jugular <input type="checkbox"/> Other <input type="checkbox"/> Unknown
E ₂ . Had this catheter (or another) been used for the past 90 days or longer prior to use in the last hemodialysis session?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
F ₁ . Was routine monitoring (screening) for the presence of stenosis performed between 10/1/98 and 12/31/98?	<input type="checkbox"/> Yes <input type="checkbox"/> No
F ₂ . If answer to question 18F ₁ is "Yes," please check all methods of monitoring (below) that were utilized. (See instructions for details.)	
<input type="checkbox"/> Color-Flow Doppler at least once between 10/1/98 and 12/31/98 <input type="checkbox"/> Static Venous Pressure at least once every 2 weeks between 10/1/98 and 12/31/98 <input type="checkbox"/> Dynamic Venous Pressure every HD session between 10/1/98 and 12/31/98 <input type="checkbox"/> Dilution Technique at least once between 10/1/98 and 12/31/98 <input type="checkbox"/> Other _____	
INSTRUCTIONS FOR COMPLETING QUESTIONS 15 THROUGH 19 (Continued from page 1): To answer questions 15 through 18, review the patient's clinic or facility medical record for OCT 1, 1998 through DEC 31, 1998. Do not leave any items blank. Enter the following if the information cannot be located: <u>NE</u> if not found, <u>HOSP</u> if hospitalized during the entire time period, <u>TRANS</u> if the patient was absent during the entire time period.	
15A: Enter the patient's FIRST serum albumin value recorded EACH month for OCT, NOV, and DEC 1998.	
15B: Check the appropriate method used by the laboratory to determine the serum albumin levels (bromocresol green or bromocresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information. DO NOT LEAVE THIS QUESTION BLANK.	
16A and 16B: Enter the patient's FIRST MONTHLY pre-dialysis hematocrit (HCT) and hemoglobin (HGB) values determined by the laboratory's Coulter Counter or other hematology instrument for EACH month - - OCT, NOV, and DEC 1998. Record <u>both</u> HCT <u>and</u> HGB <u>only</u> if they were drawn on the same date. DO NOT record any spun HCT value performed by the dialysis facility UNLESS YOUR FACILITY DOES NOT OBTAIN LABORATORY HEMATOCRIT LEVELS.	
16C: Enter the PRESCRIBED WEEKLY EPO DOSE at the time IMMEDIATELY BEFORE the hematocrit/hemoglobin measures reported in 16A and 16B were obtained, even if the patient did not receive the EPO dose ("Immediately before" refers to the week prior to the test). If prescribed less frequently than weekly, divide the EPO dose by the number of weeks prescribed to obtain weekly EPO dose OR if using the sliding scale for EPO dosing or giving EPO at each treatment, total all the doses given during the week and enter the value. Check the appropriate box to indicate if the EPO was ADMINISTERED AS PRESCRIBED. If there was NO PRESCRIPTION FOR EPO, check "No Prescription."	
16D: Check the appropriate space to indicate the prescribed route of administration for EPO (intravenous (IV) or subcutaneous (SC)).	
16E: Enter the patient's FIRST MONTHLY ferritin value recorded in EACH month for which data are available during the months of OCT, NOV, and DEC 1998. If ferritin test was not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).	
16F: Enter the patient's FIRST MONTHLY transferrin saturation value recorded in EACH month for which data are available during the months of OCT, NOV, and DEC 1998. If transferrin saturation test was not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).	
16G: Check either "Yes" or "No" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 1998.	
16H: If the answer to 16F is "Yes," please check the appropriate space to indicate the route of iron administration (intravenous (IV) or by mouth (P.O.)) each month for the months of OCT, NOV, and DEC 1998. If patient received iron by mouth and IV, please check both spaces.	
17A: Please indicate the number of dialysis sessions this patient was scheduled to receive per week in OCT, NOV, and DEC 1998. If the prescription varied during a month, enter the prescription in effect for the first week of that month.	
17B and 17C: Enter the patient's FIRST pre-and post-dialysis BUN values recorded EACH month for OCT, NOV, and DEC 1998. The pre-and post-dialysis BUN values must be drawn on the same date. If pre- and post-dialysis BUNs are only performed quarterly, enter the values for the month when performed and record "NP" (i.e., not performed) for the other two months.	
17D: Enter the patient's PRE- and POST-dialysis weight at the session when the pre- and post-dialysis BUN levels were drawn. Circle either lbs or kgs as appropriate.	

Appendix 3. (Continued)

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)	
17E:	Enter the patient's ACTUAL DELIVERED time on dialysis during the session when the BUN levels were drawn. DO NOT ENTER THE PRESCRIBED TIME ON DIALYSIS. If using finish time minus start time to calculate actual delivered time on dialysis, deduct time for any interruptions in dialysis which occurred.
17F:	Please record the delivered blood flow rate in ml/min at 60 min. into the hemodialysis session. Do not record the prescribed blood flow rate or the highest achieved blood flow rate.
17G:	Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used on the date the blood samples were drawn for the pre- and post-dialysis BUNs in OCT, NOV, and DEC 1998. If the dialyzer used is not listed on the chart, enter the code for "other" (9999).
17H and 17I:	Enter the patient's FIRST URR recorded each month for OCT, NOV, and DEC 1998. If both Kt/V and URR were recorded for this patient, please enter both.
17J:	<p>Check the box which describes the method used by your dialysis center or its designee to calculate Kt/V. Definitions for UKM and Daugirdas II appear below. If you know the method used but it is NOT either UKM or Daugirdas II, please check the "Other" box and write in the method used. If you do not know the method used, please check "Unknown"</p> <p>UKM: Please check the box marked "UKM" if you know that the method used by your dialysis center or its designee to calculate Kt/V is formal urea kinetic modeling, using the single-pool, variable-volume model. Please refer to pages 25-39 of the NKF/DOQI Clinical Practice Guidelines for Hemodialysis Adequacy for information about formal urea kinetic modeling.</p> <p>Daugirdas II: Please check the box marked "Daugirdas II" if you know that the method used by your dialysis center or its designee to calculate Kt/V is the Daugirdas II equation, as follows:</p> $Kt/V = -\ln(R - 0.008 \times t) + (4 - 3.5 \times R) \times UF/W$ <p>in which Ln is the natural logarithm; R is the post-dialysis BUN divided by the pre-dialysis BUN; t is the dialysis session length in hours; UF is the ultrafiltration volume in liters; and W is the patient's post-dialysis weight in kilograms.</p>
18.	HCFA form 2728 has the following definition of the date a patient began a regular course of dialysis: "The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of ESRD regardless of the dialysis setting. The date of the first dialysis treatment after the physician determined that the patient has ESRD and has written a prescription for a 'regular course of dialysis' is the 'Date Regular Dialysis Began' regardless of whether this prescription was implemented in a hospital, inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription."
18A:	Check the appropriate space to indicate type of vascular access used at initiation of the first maintenance course of hemodialysis for end-stage renal disease. Exclude patients who have changed dialysis modality from peritoneal dialysis or who have had previous renal transplant. Also exclude patients who have received intermittent dialysis treatments for volume overload or congestive heart failure.
18B:	Write in the date when the vascular access noted in question 18A was placed. If the date is not known, check the box marked "Unknown."
18C:	Check the appropriate space to indicate type of vascular access in use 90 days after the initiation date of hemodialysis, regardless of setting.
18D:	Check the appropriate space to indicate type of vascular access used on last hemodialysis session on or between OCT 1, 1998 and DEC 31, 1998 at the patient's primary in-center facility . Exclude dialysis sessions performed at temporary facilities because of holiday travel or hospitalizations.
18E₁ and 18E₂:	Complete 18E ₁ and 18E ₂ only if vascular access used on most recent dialysis session was a catheter .
18E₁:	If the vascular access marked for question 18D was a catheter, indicate in the appropriate space the vascular insertion location of the catheter.
18E₂:	If the vascular access marked for question 18D was a catheter, indicate in the appropriate space if one or more catheters had been used continuously in this patient for the past 90 days or longer .
18F₁ and 18F₂:	Complete 18F ₁ -18F ₂ only if vascular access used on most recent dialysis session was a synthetic or bovine graft .
18F₁:	If the vascular access marked for question 18D was a synthetic or bovine graft, indicate if there was routine monitoring (screening) for the presence of stenosis between OCT 1, 1998 and DEC 31, 1998. Routine monitoring or screening is the sequential measurement of access flow or venous pressure. The appropriate interval between sequential measurements depends on the technique used to monitor for stenosis, and is described below. For the purpose of this review , techniques used to monitor access flow include a) one of the dilution methods in which the needles are reversed and recirculation is deliberately induced, or b) conventional color-flow Doppler. In the former, the dilution indicator may be a change in 1) the velocity of ultrasound in blood, 2) hemoglobin/hematocrit, 3) temperature, 4) solute concentration, or 5) conductivity. Pump blood flow must be accurately measured to use this technique. Techniques used to monitor venous pressure include dynamic and static venous dialysis pressures. Dynamic venous pressure monitoring uses low blood pump flow rates usually set at 200 ml per minute. Static pressure monitoring is performed at zero blood pump flow. If access flow was monitored, it should have been measured on a regular basis by one of the available dilution techniques or by conventional color-flow Doppler at a minimum frequency of once every three months . If dynamic venous pressure was monitored it should have been measured at every hemodialysis session . If static venous pressure was monitored it should have been measured at a minimum frequency of once every two weeks . For the purpose of this review , clinical assessment such as prolonged bleeding after needle withdrawal, or altered characteristics of thrill or bruit, as well as dialysis adequacy measurements using Kt/V or URR, supplement, but do NOT constitute monitoring techniques. For the purpose of this review , recirculation methods do NOT constitute, monitoring for the presence of AV graft stenosis.
18F₂:	If the vascular access marked for question 18D was a synthetic or bovine graft, check all monitoring methods utilized based on the definitions and intervals given above in 18F ₁ . If other techniques and/or corresponding intervals were used check "other" and write in the technique and corresponding intervals.

Appendix 4. 1999 CPM Data Collection Form — Peritoneal Dialysis

PERITONEAL DIALYSIS (PD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: 1999

[Before completing please read instructions at the bottom of this page and on pages 5 and 6]

PATIENT IDENTIFICATION	MAKE CORRECTIONS TO PATIENT INFORMATION ON LEFT IN THE SPACE BELOW
<div style="background-color: #e0e0e0; width: 80%; margin: 0 auto; padding: 10px;"> PLACE PATIENT DATA LABEL HERE </div>	
10a. Is Patient Hispanic? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
11. If the above patient information is incorrect make corrections in space above then continue to question 12. Please verify patient's race and check question 10a. above. If patient unknown or was not dialyzed in the unit at any time during Oct 1998 – Mar 1999 return the form to the Network.	
12. Patient's height (MUST COMPLETE): _____ inches _____ centimeters	
13. Does patient have limb amputation(s): <input type="checkbox"/> Yes <input type="checkbox"/> No	
14. The most RECENT date this patient initiated (or re-initiated) any form of dialysis was: ____/____/____ [NOTE: This date may be different than the date this patient FIRST initiated dialysis; item 8, above.]	
PLEASE COMPLETE ITEMS 15 THROUGH 19 ON PAGES 2, 3 AND 4 OF THIS DATA COLLECTION FORM; INSTRUCTIONS ARE ON PAGES 5 AND 6.	
Individual Completing Form (Please print) :	
First name: _____ Last name: _____ Title: _____	
Phone number: (____) _____ - _____ Fax number (____) _____ - _____	

INSTRUCTIONS FOR COMPLETING THE PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: 1999

The label on the top left side of this form (#'s 1-8) contains the following patient identifying information. If the information is incorrect make corrections to the right of the label.

- | | |
|---|--|
| 1. LAST and first name.
3. SOCIAL Security Number (SSN).
5. SEX (M=Male; F=Female; U=Unknown).
7. PRIMARY cause of renal failure by HCFA-2728 code.
9. ESRD Network number. Do not make corrections to this item. | 2. DATE of birth (DOB) as MM/DD/YYYY.
4. HEALTH Insurance Claim Number (HIC).
6. RACE (0=Unknown; 1=White; 2=Black; 3=Other; 4=Asian/Pacific Islander; 6= American Indian/Alaska Native).
8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
10. Facility's Medicare provider number.
10a. Is the patient Hispanic? Check either Yes, No, or Unknown, as appropriate. |
|---|--|
11. Review the patient and facility specific information contained on the pre-printed label. Please verify the patient's race, item 6 above. If any of the information is incorrect, write corrections in the space to the right of the label. If the patient is unknown or if the patient was not dialyzed in the unit at any time during Nov - Dec 1998 & Jan - Mar 1999, send the form back to the ESRD Network office with the name and address of the facility providing services to this patient on March 30, 1999, if known.
12. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank, you may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height and check YES for item 13.
13. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but check YES if this Patient has had a below-knee, below-elbow, or more proximal (extensive) amputation.
14. Enter the most recent date this patient initiated (or re-initiated) any form of dialysis. This date may be different than the date this patient first initiated dialysis (item 8), e.g., the patient may have re-initiated dialysis after a failed transplantation.

PLEASE COMPLETE ITEMS 15 THROUGH 19 ON PAGES 2, 3, AND 4 OF THIS DATA COLLECTION FORM.
INSTRUCTIONS FOR COMPLETING THESE ITEMS ARE ON PAGES 5 AND 6.

Appendix 4. (Continued)

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)			
15. SERUM ALBUMIN: Enter the FIRST monthly serum albumin FOR EACH 2-MONTH TIME PERIOD: OCT-NOV 1998, DEC 1998-JAN 1999, FEB-MAR 1999. Check the method used by lab to determine the serum albumins. If method unknown, please call lab to find out. Do not leave blank.			
	OCT-NOV 1998	DEC 1998-JAN 1999	FEB-MAR 1999
A. First monthly serum albumin:	_____ gm/dL	_____ gm/dL	_____ gm/dL
B. Check lab method used (BCG=bromcresol green; BCP=bromcresol purple)	<input type="checkbox"/> BCGreen <input type="checkbox"/> BCPurple	<input type="checkbox"/> BCGreen <input type="checkbox"/> BCPurple	<input type="checkbox"/> BCGreen <input type="checkbox"/> BCPurple
LAB DATA. The following data are requested for each month OCTOBER 1998 through MARCH 1999. For each question, where appropriate use the first lab values obtained in each month. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: NF if Not Found. HOSP if patient was hospitalized during the entire time period. TRANS if patient was absent during the entire time period.			
16. HEMATOCRIT: Enter the FIRST Hematocrit (HCT) and Hemoglobin (HGB) determined by lab's Coulter Counter or other hematology instrument FOR EACH MONTH OCT 1998 THROUGH MAR 1999. Record both HCT and HGB only if both were drawn on the same date. DO NOT ENTER SPUN HCT VALUE, unless your facility does not obtain lab HCTs. Also enter the prescribed WEEKLY EPO dose and the route of administration, the first monthly Ferritin and Transferrin Saturation value, and the route of iron administration.			
	OCT 1998	NOV 1998	DEC 1998
A. First monthly pre-dialysis laboratory hematocrit:	_____ %	_____ %	_____ %
B. First monthly pre-dialysis laboratory hemoglobin:	_____ g/dL	_____ g/dL	_____ g/dL
C. What was the PRESCRIBED WEEKLY EPO dose at the time immediately BEFORE the above HCT/HGB were drawn?	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription
D. What was the prescribed route of EPO administration related to item 16C?	_____ IV _____ SC	_____ IV _____ SC	_____ IV _____ SC
E. First monthly Ferritin value:	_____ ng/mL	_____ ng/mL	_____ ng/mL
F. First monthly Transferrin Saturation value:	_____ %	_____ %	_____ %
G. Was iron prescribed at any time during the month?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No
H. If yes, what was the route of administration? (check all that apply)	_____ IV _____ P.O.	_____ IV _____ P.O.	_____ IV _____ P.O.
	JAN 1999	FEB 1999	MAR 1999
A. First monthly pre-dialysis laboratory hematocrit:	_____ %	_____ %	_____ %
B. First monthly pre-dialysis laboratory hemoglobin:	_____ g/dL	_____ g/dL	_____ g/dL
C. What was the PRESCRIBED WEEKLY EPO dose at the time immediately BEFORE the above HCT/HGB were drawn?	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription	_____ units/wk Was EPO administered? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No Prescription
D. What was the prescribed route of EPO administration related to item 16C?	_____ IV _____ SC	_____ IV _____ SC	_____ IV _____ SC
E. First monthly Ferritin value:	_____ ng/mL	_____ ng/mL	_____ ng/mL
F. First monthly Transferrin Saturation value:	_____ %	_____ %	_____ %
G. Was iron prescribed at any time during the month?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No
H. If yes, what was the route of administration? (check all that apply)	_____ IV _____ P.O.	_____ IV _____ P.O.	_____ IV _____ P.O.
17. PERITONEAL DIALYSIS ADEQUACY: The remainder of this form lists a series of questions regarding adequacy measurements for this patient. Please answer questions 17 A and B for the 2-MONTH time periods indicated. Then continue to pages 3 and 4.			
	OCT - NOV 1998	DEC 1998 - JAN 1999	FEB - MAR 1999
A. Was the patient on peritoneal dialysis at any time during this period?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No
B. Was the patient on hemodialysis or did patient receive a transplant at any time during this period?	_____ Yes _____ No	_____ Yes _____ No	_____ Yes _____ No

Appendix 4. (Continued)

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)				
18. ADEQUACY: The following data are requested for each adequacy determination during the months OCTOBER 1998 through MARCH 1999. Starting with the first adequacy measurement in these months enter the adequacy measurements/results listed below that were obtained FOR EACH adequacy measurement done. (Please do not record more than one adequacy measurement done for any one month.) Please read instructions on pages 5 and 6 before completing this section.				
A. Date for each adequacy measurement from 10-1-98 to 3-31-99	____/____/____ (mm) (dd) (yy)		____/____/____ (mm) (dd) (yy)	
B. Patient's dialysis modality when adequacy measures below were performed?	<input type="checkbox"/> CAPD <input type="checkbox"/> APD <input type="checkbox"/> TIDAL		<input type="checkbox"/> CAPD <input type="checkbox"/> APD <input type="checkbox"/> TIDAL	
C. Patient's weight at the time of this adequacy assessment (abdomen empty): (Circle lbs or kgs)	_____ lbs / kgs		_____ lbs / kgs	
D. Weekly Kt/V _{urea} calculated at the time of this adequacy measurement:	_____		_____	
E. Method by which V above was calculated: (check one; See instructions on page 5)	____ %BW ____ Hume ____ Watson ____ Other		____ %BW ____ Hume ____ Watson ____ Other	
F. Weekly Creatinine Clearance:	_____ L/wk		_____ L/wk	
G. Is this Creatinine Clearance corrected for body surface area, using standard methods? (see instructions on page 6)	____ Yes ____ No		____ Yes ____ No	
H. 24 hr DIALYSATE outflow volume:	_____ mL		_____ mL	
I. 24 hr DIALYSATE urea nitrogen:	_____ mg/dL		_____ mg/dL	
J. 24 hr DIALYSATE creatinine:	_____ mg/dL		_____ mg/dL	
K. 24 hr URINE volume: (If 24 hr urine was not collected check NP. If patient's urine production was negligible, i.e., <200 cc of urine/24 hr., then check anuric and go to question 18N)	_____ mL ____ NP ____ anuric		_____ mL ____ NP ____ anuric	
L. 24 hr URINE urea nitrogen:	_____ mg/dL		_____ mg/dL	
M. 24 hr URINE creatinine:	_____ mg/dL		_____ mg/dL	
N. SERUM BUN at the time this adequacy assessment was done:	_____ mg/dL		_____ mg/dL	
O. SERUM creatinine at the time this adequacy assessment was done:	_____ mg/dL		_____ mg/dL	
19. PERITONEAL DIALYSIS PRESCRIPTION: For the following questions – record the PD prescription in effect immediately prior to the time the adequacy measures/results recorded in Question 18 were performed. In addition, if the prescription was changed following the adequacy measurement, please record the new prescription in the column indicated. Please read instructions on Page 6 before completing this section.				
	Prescription prior to date in 18A	New Prescription ▶ ____/____/____ (mm) (dd) (yy)	Prescription prior to date in 18A	New Prescription ▶ ____/____/____ (mm) (dd) (yy)
A. Does the prescription described below include TIDAL dialysis?	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No
B. Number of dialysis days per week	____ (# days)	____ (# days)	____ (# days)	____ (# days)
C. CAPD PRESCRIPTION (for patients on CAPD, including patients with an overnight exchange using an assist device)				
1. Total dialysate volume infused per 24 hours	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs
2. Total number of exchanges per 24 hours (including overnight exchange)	____ (# exchanges)	____ (# exchanges)	____ (# exchanges)	____ (# exchanges)
D. APD/TIDAL PRESCRIPTION				
1. Total dialysate volume infused per 24 hours	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs
2. NIGHTTIME PRESCRIPTION DATA				
a. Total nighttime dialysis dwell time	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min
b. Total nighttime dialysate volume, excluding last bag option	_____ mL/nighttime	_____ mL/nighttime	_____ mL/nighttime	_____ mL/nighttime
c. Number of dialysis exchanges during the nighttime	____ (#/nighttime)	____ (#/nighttime)	____ (#/nighttime)	____ (#/nighttime)
3. DAYTIME PRESCRIPTION DATA				
a. Total daytime dialysis dwell time	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min
b. Total daytime dialysate volume, including last bag option	_____ mL/daytime	_____ mL/daytime	_____ mL/daytime	_____ mL/daytime
c. Number of dialysis exchanges during the daytime	____ (#/daytime)	____ (#/daytime)	____ (#/daytime)	____ (#/daytime)
E. Based on this adequacy result,				
1. Was the collection repeated?	____ Yes ____ No		____ Yes ____ No	
2. Was the prescription changed?	____ Yes ____ No		____ Yes ____ No	
If the prescription was changed, enter new prescription and date of new prescription in column indicated.	New Prescription		New Prescription	

continued ↓

continued ↓

Appendix 4. (Continued)

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)				
18. ADEQUACY: The following data are requested for each adequacy determination during the months OCTOBER 1998 through MARCH 1999. Starting with the first adequacy measurement in these months enter the adequacy measurements/results listed below that were obtained FOR EACH adequacy measurement done. (Please do not record more than one adequacy measurement done for any one month.) Please read instructions on pages 5 and 6 before completing this section.				
A. Date for each adequacy measurement from 10-1-98 to 3-31-99	____/____/____ (mm) (dd) (yy)		____/____/____ (mm) (dd) (yy)	
B. Patient's dialysis modality when adequacy measures below were performed?	<input type="checkbox"/> CAPD <input type="checkbox"/> APD <input type="checkbox"/> TIDAL	<input type="checkbox"/> CAPD <input type="checkbox"/> APD <input type="checkbox"/> TIDAL		
C. Patient's weight at the time of this adequacy assessment (abdomen empty): (Circle lbs or kgs)	_____ lbs / kgs		_____ lbs / kgs	
D. Weekly Kt/V _{urea} calculated at the time of this adequacy measurement:	_____		_____	
E. Method by which V above was calculated: (check one; See instructions on page 5)	____ %BW ____ Hume ____ Watson ____ Other		____ %BW ____ Hume ____ Watson ____ Other	
F. Weekly Creatinine Clearance:	_____ L/wk		_____ L/wk	
G. Is this Creatinine Clearance corrected for body surface area, using standard methods? (see instructions on page 6)	____ Yes ____ No		____ Yes ____ No	
H. 24 hr DIALYSATE outflow volume:	_____ mL		_____ mL	
I. 24 hr DIALYSATE urea nitrogen:	_____ mg/dL		_____ mg/dL	
J. 24 hr DIALYSATE creatinine:	_____ mg/dL		_____ mg/dL	
K. 24 hr URINE volume: (If 24 hr urine was not collected check NP. If patient's urine production was negligible, i.e., <200 cc of urine/24 hr., then check anuric and go to question 18N)	_____ mL ____ NP ____ anuric		_____ mL ____ NP ____ anuric	
L. 24 hr URINE urea nitrogen:	_____ mg/dL		_____ mg/dL	
M. 24 hr URINE creatinine:	_____ mg/dL		_____ mg/dL	
N. SERUM BUN at the time this adequacy assessment was done:	_____ mg/dL		_____ mg/dL	
O. SERUM creatinine at the time this adequacy assessment was done:	_____ mg/dL		_____ mg/dL	
19. PERITONEAL DIALYSIS PRESCRIPTION: For the following questions – record the PD prescription in effect immediately prior to the time the adequacy measures/results recorded in Question 18 were performed. In addition, if the prescription was changed following the adequacy measurement, please record the new prescription in the column indicated. Please read instructions on Page 6 before completing this section.				
	Prescription prior to date in 18A	New Prescription → ____/____/____ (mm) (dd) (yy)	Prescription prior to date in 18A	New Prescription → ____/____/____ (mm) (dd) (yy)
A. Does the prescription described below include TIDAL dialysis?	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No
B. Number of dialysis days per week	_____ (# days)	_____ (# days)	_____ (# days)	_____ (# days)
C. CAPD PRESCRIPTION (for patients on CAPD, including patients with an overnight exchange using an assist device)				
1. Total dialysate volume infused per 24 hours	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs
2. Total number of exchanges per 24 hours (including overnight exchange)	____ (# exchanges)	____ (# exchanges)	____ (# exchanges)	____ (# exchanges)
D. APD/TIDAL PRESCRIPTION				
1. Total dialysate volume infused per 24 hours	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs	_____ mL/24 hrs
2. NIGHTTIME PRESCRIPTION DATA				
a. Total nighttime dialysis dwell time	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min
b. Total nighttime dialysate volume, excluding last bag option	_____ mL/nighttime	_____ mL/nighttime	_____ mL/nighttime	_____ mL/nighttime
c. Number of dialysis exchanges during the nighttime	____ (#/nighttime)	____ (#/nighttime)	____ (#/nighttime)	____ (#/nighttime)
3. DAYTIME PRESCRIPTION DATA				
a. Total daytime dialysis dwell time	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min
b. Total daytime dialysate volume, including last bag option	_____ mL/daytime	_____ mL/daytime	_____ mL/daytime	_____ mL/daytime
c. Number of dialysis exchanges during the daytime	____ (#/daytime)	____ (#/daytime)	____ (#/daytime)	____ (#/daytime)
E. Based on this adequacy result,				
1. Was the collection repeated?	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No
2. Was the prescription changed?	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No	____ Yes ____ No
If the prescription was changed, enter new prescription and date of new prescription in column indicated.	New Prescription _____	New Prescription _____	New Prescription _____	New Prescription _____

Appendix 4. (Continued)

Page 5

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)
INSTRUCTIONS FOR COMPLETING QUESTIONS 15 THROUGH 19 (continued from page 1)
To answer questions 15 through 19 review the patient's clinic or facility medical record for each two-month period: OCT 1, 1998 through NOV 30, 1998, DEC 1, 1998 through JAN 31, 1999, and FEB 1, 1999 through MAR 31, 1999. Do not leave any items blank. Enter the following if the information cannot be located: <u>NF</u> if not found, <u>HOSP</u> if hospitalized during the entire time period, <u>TRANS</u> if patient was absent during the entire time period.
15A: Enter the patient's FIRST serum albumin value recorded EACH 2-Month time period: OCT-NOV 1998, DEC 1998-JAN1999, FEB-MAR 1999
15B: Check the appropriate method used by the laboratory to determine the serum albumin levels (bromocresol green or bromocresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information. DO NOT LEAVE THIS QUESTION BLANK.
16A and 16B: Enter the patient's FIRST MONTHLY pre-dialysis hematocrit (HCT) and hemoglobin (HGB) values determined by the laboratory's Coulter Counter or other hematology instrument for EACH month - - OCT 1998 through MAR 1999. Record <u>both</u> HCT and HGB <u>only</u> if they were drawn on the same date. DO NOT record any spun HCT value performed by the dialysis facility UNLESS YOUR FACILITY DOES NOT OBTAIN LABORATORY HEMATOCRIT LEVELS.
16C: Enter the PRESCRIBED WEEKLY EPO DOSE at the time IMMEDIATELY BEFORE the hematocrit/hemoglobin measures reported in 16A and 16B were obtained, even if the patient did not receive the EPO dose ("Immediately before" refers to the week prior to the test). If prescribed less frequently than weekly, divide the EPO dose by the number of weeks prescribed to obtain weekly EPO dose OR if using the sliding scale for EPO dosing or giving EPO at each treatment, total all the doses given during the week and enter the value. Check the appropriate box to indicate if the EPO was ADMINISTERED AS PRESCRIBED. If there was NO PRESCRIPTION FOR EPO, check "No Prescription."
16D: Check the appropriate space to indicate the prescribed route of administration for EPO (intravenous (IV) or subcutaneous (SC)).
16E: Enter the patient's FIRST MONTHLY ferritin value recorded in EACH month for which data are available during the months of OCT 1998 through MAR 1999. If ferritin test was not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).
16F: Enter the patient's FIRST MONTHLY transferrin saturation value recorded in EACH month for which data are available during the months of OCT 1998 through MAR 1999. If transferrin saturation test was not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).
16G: Check either "Yes" or "No" to indicate if iron was prescribed at any time during the months of OCT 1998 through MAR 1999.
16H: If the answer to 16F is "Yes," please check the appropriate space to indicate the route of iron administration (intravenous (IV) or by mouth (P.O.)) each month for the months OCT 1998 through MAR 1999. If patient received iron by mouth <u>and</u> IV, please check both spaces.
17A: Check the appropriate response (yes or no) for each two-month interval, indicating whether this patient was on peritoneal dialysis at any time during each of the specified two-month intervals: OCT 1, 1998 through NOV 30, 1998; DEC 1, 1998 through JAN 31, 1999; and FEB 1, 1999 through MAR 31, 1999.
17B: Check the appropriate response (yes or no) for each two-month interval, indicating whether this patient was on hemodialysis or received a transplant at any time during each of the specified two-month intervals: OCT 1, 1998 through NOV 30, 1998; DEC 1, 1998 through JAN 31, 1999; and FEB 1, 1999 through MAR 31, 1999.
18A: Enter the date on which adequacy of dialysis was assessed for each measure obtained between OCT 1, 1998 through MAR 31, 1999 up to a maximum of four adequacy measures. [Note: spaces to answer items 18 and 19 appear on page 4 as well as page 3.]
18B: Check the modality of peritoneal dialysis this patient was on at the time the corresponding adequacy of dialysis measure was obtained. CHECK either CAPD, APD or TIDAL. If the patient was on more than one modality in the four weeks preceding the date entered on 18A, check all applicable modalities. TIDAL patients are Cycler patients for whom the dialysate is partially drained between some exchanges.
18C: Enter the patient's weight (with abdomen empty) at the clinic/facility visit when the adequacy measurements were obtained, circle lbs or kgs as appropriate.
18D & 18F: Enter the TOTAL WEEKLY Kt/V_{urea} and/or WEEKLY CREATININE CLEARANCE for each adequacy measurement indicated on 18A between OCT 1, 1998 through MAR 31, 1999. NOTE: If you have a value for weekly Kt/V_{urea} (or creatinine clearance) for a particular adequacy assessment, please complete the corresponding values for questions 18H through 18J for 24-hour dialysate volume, 24-hour dialysate urea (or creatinine) and, if the patient is not anuric, the 24-hour urine urea (or creatinine), if these values are available. If Kt/V_{urea} or creatinine clearance results were only measured quarterly or each 6 months, enter the FIRST value obtained during the six-month time period between OCT 1, 1998 through MAR 31, 1999 under the corresponding date entered in 18A and enter NP for all time periods when not performed. If your unit calculates a daily Kt/V_{urea} or daily creatinine clearance, multiply this result by 7.0 and enter the result in the appropriate space(s). If this patient did not dialyze each day of the week, then multiply the daily Kt/V_{urea} or daily creatinine clearance by the number of days the patient did dialyze.

Appendix 4. (Continued)

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM: (CONTINUED)	
18E:	Check the method used to calculate the V in the Kt/V_{urea} measurement; % BW = percent of body weight; Hume and Watson are two nomograms used to calculate V based on several of these parameters - weight, height, age, gender. If method used to calculate V is not known, please call lab to ascertain method. Please do not leave blank.
18G:	Check Yes or No if the weekly creatinine clearance was normalized for body surface area (i.e., the result is multiplied by the patient's body surface area (BSA) and divided by $1.73m^2$). Standard methods for establishing BSA are: the DuBois and DuBois method; the Gehan and George method; and the Haycock method. If you do not have this information, call the laboratory that provided the weekly Kt/V_{urea} or creatinine clearance value for this information. Please do not leave blank.
18 H, I, and J:	Enter the measured 24 hour DIALYSATE outflow volume, urea nitrogen and creatinine obtained for the adequacy measurement obtained for each date indicated in 18A. If a 24 hr dialysate outflow volume, urea nitrogen or creatinine were NOT measured at that time, enter NP (for not performed) in the appropriate spaces. ONLY ENTER ACTUAL MEASURED 24 HOUR DIALYSATE VOLUME. DO NOT ENTER AN EXTRAPOLATED DIALYSATE VOLUME. Please report the dialysate outflow or drain volume, NOT the prescribed volume.
18K, L, and M:	Enter the 24-hour URINE volume, urea nitrogen and creatinine obtained for the adequacy assessment obtained for each date indicated in 18A. ONLY ENTER ACTUAL MEASURED 24-HR URINE VOLUME--DO NOT ENTER AN EXTRAPOLATED URINE VOLUME. If 24-hour urine volume was not collected check NP for not performed, OR if the patient's urine production was negligible, i.e., <200 cc of urine/24 hours, then check anuric. If NP or anuric is checked, SKIP TO QUESTION 18N. If urine urea nitrogen and creatinine were only measured quarterly or every six months, enter the FIRST value obtained for the six-month period in the column with the corresponding date entered on 18A and enter NP for all other time periods when not performed.
18N and 18O:	Enter the SERUM BUN and SERUM CREATININE obtained for each adequacy assessment during the six-month time period between OCT 1, 1998 through MAR 31, 1999. If adequacy assessment measurements are only obtained quarterly or each six months, enter serum BUN and creatinine results for the corresponding dialysate data in 18H through 18J and enter NP in the appropriate spaces for all time periods when not performed.
19:	To respond to questions 19A through 19E record the peritoneal dialysis (PD) prescription in effect immediately prior to the time the adequacy measures/results recorded in question 18 were performed. In addition, if the prescription was changed following the adequacy measurement, please record the new prescription in the column labeled "New Prescription" as well as indicating the date that the new prescription was initiated. Complete all items that are applicable.
19A:	Check the appropriate box, yes or no, whether this patient's peritoneal dialysis prescription included TIDAL dialysis. TIDAL patients are Cycler patients for whom the dialysate is partially drained between some exchanges.
19B:	Enter the number of days per week for which this patient undergoes peritoneal dialysis.
19C:	CAPD PRESCRIPTION. Use the CAPD prescription category for all CAPD patients including patients with overnight exchange(s) using an assist device. Enter the total dialysate <u>volume</u> infused over a 24-hour period and the <u>number of exchanges per 24-hour period</u> PRESCRIBED for CAPD at the time the adequacy measures in question 18 were performed for each adequacy measure specified in 18A.
19D:	APD/TIDAL PRESCRIPTION. Enter the total dialysate volume infused over a 24-hour period. CYCLER NIGHTTIME PRESCRIPTION. Use the CYCLER NIGHTTIME prescription category for Cycler and Tidal patients only. Enter the <u>total nighttime dialysis dwell time</u> , the <u>total nighttime dialysate inflow volume for a 24-hour period</u> , and <u>number of dialysis exchanges completed during the nighttime</u> PRESCRIBED for CYCLER NIGHTTIME at the time the adequacy measures in question 18 were performed for each adequacy measure identified in question 18A. Include in the CYCLER NIGHTTIME prescription only those exchanges provided by an automated device. DO NOT include in this category any wet day prescriptions (i.e., a last dwell fill that the patient carries after unhooking from the cycler or any daytime dwells) as these exchanges are recorded in the CYCLER DAYTIME prescription below. If different inflow volumes are used, report average inflow volume. CYCLER DAYTIME PRESCRIPTION. Use CYCLER DAYTIME prescription category for Cycler and Tidal patients only. Enter the <u>total daytime dialysis dwell time</u> , the <u>total daytime dialysate inflow volume for a 24-hour period</u> , and <u>number of daytime exchanges per 24 hour period</u> PRESCRIBED for CYCLER DAYTIME at the time the adequacy measures in question 18 were performed for each adequacy measure identified in question 18A. INCLUDE in the CYCLER DAYTIME prescription only those exchanges performed after the patient disconnects from the cycler and/or a last dwell fill that the patient carries during the day (e.g., WET DAY PRESCRIPTION). ANY OTHER EXCHANGES PERFORMED USING THE CYCLER SHOULD BE INCLUDED UNDER CYCLER NIGHTTIME PRESCRIPTION. If different inflow volumes are used, report average inflow volume.
19E:	Check the appropriate box, yes or no, indicating whether the adequacy collection was repeated, or the prescription changed, following the adequacy measure performed on the date indicated on line 18A. If the prescription was changed enter the new prescription in the column to the right.

Appendix 5. 1999 CPM Facility-Specific Data Collection Form

**FACILITY CLINICAL PERFORMANCE
MEASURES DATA COLLECTION FORM: 1999**

<p>FACILITY IDENTIFICATION</p>	<p align="center">MAKE CORRECTIONS TO FACILITY INFORMATION ON LEFT IN THE SPACE BELOW</p>		
<div style="background-color: #cccccc; width: 80%; margin: 0 auto; padding: 10px;"> <p>PLACE FACILITY DATA LABEL HERE</p> </div>			
<p>1. Which of the following would best describe your facility's written policy for the TIMING of the post-dialysis BUN sample collection as of October 1, 1998? <i>(This question refers to any written policy, endorsed by your facility's management and to which adherence is expected, regarding the timing of blood draws for the assessment of post-dialysis BUN samples. Please mark the box "No Policy" if there is none.)</i> [CHECK ONLY ONE ANSWER]</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Immediately, without slowing blood flow <input type="checkbox"/> 15 to 60 seconds after slowing or stopping blood flow <input type="checkbox"/> > 15 minutes </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Immediately after slowing or stopping blood flow <input type="checkbox"/> 1 to 2 minutes after slowing or stopping blood flow <input type="checkbox"/> No Policy </td> </tr> </table>		<input type="checkbox"/> Immediately, without slowing blood flow <input type="checkbox"/> 15 to 60 seconds after slowing or stopping blood flow <input type="checkbox"/> > 15 minutes	<input type="checkbox"/> Immediately after slowing or stopping blood flow <input type="checkbox"/> 1 to 2 minutes after slowing or stopping blood flow <input type="checkbox"/> No Policy
<input type="checkbox"/> Immediately, without slowing blood flow <input type="checkbox"/> 15 to 60 seconds after slowing or stopping blood flow <input type="checkbox"/> > 15 minutes	<input type="checkbox"/> Immediately after slowing or stopping blood flow <input type="checkbox"/> 1 to 2 minutes after slowing or stopping blood flow <input type="checkbox"/> No Policy		
<p>2. During the time period January 1, 1998 to December 31, 1998, did your facility conduct an audit of adherence to the written policy for post-dialysis BUN sample collection? <i>(An audit refers to an actual physical observation and verification of post-dialysis BUN blood sample draws in order to assess compliance with the policy identified in question A.)</i></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>			
<p>3. During the time period October 1, 1998 to December 31, 1998 did your facility re-process (re-use) dialyzers? <i>(Please answer "Yes" if your facility re-used ≥ 1 dialyzer(s) between October 1, 1998 and December 31, 1998.)</i></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p> <p><u>If yes</u>, please check the box(es) which most accurately represents the proportion of reprocessed dialyzers for which total cell volume (TCV) is measured in your facility prior to first use: [CHECK ALL THAT APPLY]</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> ____% <input type="checkbox"/> We use the dialyzer manufacturer's product information to infer TCV <input type="checkbox"/> We use batch testing and/or an average TCV for a group of hemodialyzers to infer TCV <input type="checkbox"/> Other _____ </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 100 % </td> </tr> </table>		<input type="checkbox"/> ____% <input type="checkbox"/> We use the dialyzer manufacturer's product information to infer TCV <input type="checkbox"/> We use batch testing and/or an average TCV for a group of hemodialyzers to infer TCV <input type="checkbox"/> Other _____	<input type="checkbox"/> 100 %
<input type="checkbox"/> ____% <input type="checkbox"/> We use the dialyzer manufacturer's product information to infer TCV <input type="checkbox"/> We use batch testing and/or an average TCV for a group of hemodialyzers to infer TCV <input type="checkbox"/> Other _____	<input type="checkbox"/> 100 %		
<p>Individual Completing Form (Please print) :</p> <p>First name: _____ Last name: _____ Title: _____</p> <p>Phone number: (____) _____ - _____ Fax number (____) _____ - _____</p>			

Appendix 6. HCFA Offices and ESRD Networks

HCFA Offices

Office of Clinical Standards and Quality
Quality Measurement and Health Assessment Group
S3-02-01
7500 Security Boulevard
Baltimore, MD 21244
(410) 786-5785

Health Care Financing Administration - Region I
Division of Clinical Standards and Quality,
Clinical Standards Branch
Room 2275
JFK Federal Building
Boston, MA 02203-0003
(617) 565-3136

Health Care Financing Administration - Region VI
Division of Clinical Standards and Quality
Room 714
1301 Young Street
Dallas, TX 75202
(214) 767-4405

Health Care Financing Administration - Region VII
Division of Clinical Standards and Quality,
Medical Review Branch
Richard Bolling Federal Building
601 East 12th Street, Room 242
Kansas City, MO 64106-2808
(816) 426-5746

Health Care Financing Administration - Region X
Division of Clinical Standards and Quality,
2201 Sixth Avenue, Mail Stop (RX-42)
Seattle, WA 98121-2500
(206) 615-2317

ESRD Networks

ESRD Network Organization No. 1
ESRD Network of New England
P.O. Box 9484
New Haven, CT 06534
Region I: ME, NH, VT, MA, CT, RI
(203) 387-9332

ESRD Network Organization No. 2
1216 Fifth Avenue
New York, NY 10029
Region I: NY
(212) 289-4524

ESRD Network Organization No. 3
Cranbury Plaza
2525 Route 130 - Bldg C
Cranbury, NJ 08512-9595
Region I: NJ, PR, VI
(908) 395-5544

ESRD Network Organization No. 4
University of Pittsburgh Medical Center
200 Lothrop Street
Pittsburgh, PA 15213-2582
Region I: PA, DE
(412) 647-3428

ESRD Network Organization No. 5
Mid-Atlantic Renal Coalition
1527 Huguenot Road
Midlothian, VA 23113
Region I: DC, MD, VA, WV
(804) 794-3757

ESRD Network Organization No. 6
Lake Plaza East
900 Ridgefield Dr., Suite 220
Raleigh, NC 27609
Region VI: GA, NC, SC
(919) 876-7545

Appendix 6. (Continued)

ESRD Network Organization No. 7
ESRD Network of Florida, Inc.
1 Davis Boulevard, Suite 304
Tampa, FL 33606
Region VI: FL
(813) 251-8686

ESRD Network Organization No. 8
Network Eight, Inc.
P.O. Box 55868
Jackson, MS 39296-5668
Region VI: AL, MS, TN
(601) 936-9260

ESRD Network Organization No. 9 & 10
The Renal Network
911 East 86th Street, Suite 202
Indianapolis, IN 46240-1858
Region VII: KY, IN, OH, IL
(317) 257-8265

ESRD Network Organization No. 11
ESRD Renal Network
of the Upper Mid-West, Inc.
970 Raymond Avenue, Suite 205
St. Paul, MN 55114
Region VII: MI, MN, WI, ND, SD
(651) 644-9877

ESRD Network Organization No. 12
Northpoint Circle II, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153
Region VII: MO, IA, NE, KS
(816) 880-9990

ESRD Network Organization No. 13
6600 N Meridan Ave, Ste 155
Oklahoma City, OK 73116-1421
Region VI: AR, LA, OK
(405) 843-8688

ESRD Network Organization No. 14
ESRD Network of Texas, Inc.
14114 Dallas Parkway, # 660
Dallas, TX 75240
Region VI: TX
(972) 503-3215

ESRD Network Organization No. 15
Intermountain ESRD Network, Inc.
1301 Pennsylvania Street, Suite 220
Denver, CO 80203-5012
Region X: NM, CO, WY, UT, AZ, NV
(303) 831-8818

ESRD Network Organization No. 16
Northwest Renal Network
4702 42d Avenue SW
Seattle, WA 98116
Region X: MT, AK, ID, OR, WA
(206) 448-1803

ESRD Network Organization No. 17
TransPacific Renal Network
25 Mitchell Boulevard
Suite 7
San Rafael, CA 94903
Region X: No. CA, HI, Mariana Isl., GU, AS
(415) 472-8590

ESRD Network Organization No. 18
Southern California Renal Disease Council
6255 Sunset Boulevard, Suite 2211
Los Angeles, CA 90028
Region X: So. CA
(323) 962-2020

Appendix 7. ESRD CPM Quality Improvement Committee Members

Evelyn Butera, MS, RN, CNN
American Nephrology Nurses Association
Satellite Dialysis Centers, Inc,
345 Convention Way, Suite B
Redwood City, CA 94063-1402

Diane Frankenfield, DrPH
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd.
Baltimore, MD 21244

Pamela Frederick, MSB
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd.
Baltimore, MD 21244

Kay Hall, BSN, RN, CNN
Health Care Financing Administration
CSQ, ROVI
1301 Young St., Rm 714
Dallas, TX 75202

Curtis Johnson, Pharm D
Professor School of Pharmacy
University of Wisconsin
425 North Charter Street
Madison, WI 53706

Linda Moore, RD
SangStat Medical Corp
7144 Donnington Dr.
Germantown, TN 38138

William F. Owen, Jr. MD
Renal Physicians Association
Duke Institute of Renal Outcomes Research
Division of Nephrology
Box 3646
Duke University Medical Center
Durham, NC 27710

Susan Raulie, RN
National Renal Administrators Association
Bay Area Dialysis Services
1125 Third Street
Corpus Christi, TX 78404

Michael Rocco, MD
Wake Forest University School of Medicine
Section of Nephrology
Medical Center Blvd.
Winston-Salem NC 27157-1053

Susan Stark
Forum of ESRD Networks
ESRD Network 9 & 10
911 East 86th St., Suite 202
Indianapolis, IN 46240

Lisa Taylor, RN
Forum of ESRD Networks
ESRD Network 12
Northpointe Circle II, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153

Jay Wish, MD
Forum of ESRD Networks
University Hospital of Cleveland
Division of Nephrology
Rm 8124, Lakeside Bldg.
2074 Abington Rd.
Cleveland, OH 44106

Appendix 7. (Continued)

ESRD CPM Quality Improvement Committee — Peritoneal Dialysis Subcommittee Members

George Bailie, Pharm D, Ph.D.
Professor, Dept of Pharmacy Practice
Albany College of Pharmacy
106 New Scotland Avenue
Albany, NY 12208-3492

Michael Flanigan, MD
Assistant Professor
Univ of Iowa Hosp & Clinic
Dept of Nephrology
Newton Road
Iowa City, IA 52242

Diane Frankenfield, DrPH
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd.
Baltimore, MD 21244

Pamela Frederick, MSB
Health Care Financing Administration
OCSQ/QMHAG
7500 Security Blvd.
Baltimore, MD 21244

Kay Hall, BSN, RN, CNN
Health Care Financing Administration CSQ, ROVI
1301 Young St., Rm 714
Dallas, TX 75202

William McClellan, MD
Georgia Medical Care Foundation
57 Executive Park South, Suite 200
Atlanta, GA 30329

Barbara Prowant, MSN, RN
Univ. of Missouri-Columbia School of Medicine
Dialysis Clinic Inc.
3300 Lemone Blvd.
Columbia, MO 65201

Michael Rocco, MD
Wake Forest University School of Medicine
Section of Nephrology
Medical Center Blvd.
Winston-Salem, NC 27157-1053

Lisa Taylor, RN
ESRD Network 12
Northpointe Circle II, Suite 105
7509 NW Tiffany Springs Parkway
Kansas City, MO 64153

Appendix 8. References

1. Consensus Development Conference Panel. Morbidity and mortality of renal dialysis: An NIH consensus conference statement. *Ann Intern Med* 1994;121:62-70.
2. 1998 ESRD facility survey (HCFA-2744) data, Health Care Financing Administration, Office of Clinical Standards and Quality. (report)
3. Lohr KN, Schroeder SA. A strategy for quality assurance in Medicare. *N Engl J Med* 1990; 322:707-712.
4. Gagel BJ. Health Care Quality Improvement Program: A New Approach. *Health Care Financing Review* 1995;16(4):15-23.
5. Vladeck BC. From the HCFA, ESRD Core Indicators Project. *JAMA* 1995;273:1896.
6. NKF-DOQI Clinical Practice Guidelines for Hemodialysis Adequacy. *Am J Kidney Dis* 1997; 30 (supplement 2).
7. NKF-DOQI Clinical Practice Guidelines for Peritoneal Dialysis Adequacy. *Am J Kidney Dis* 1997; 30 (supplement 2).
8. NKF-DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure. *Am J Kidney Dis* 1997; 30 (supplement 3).
9. NKF-DOQI Clinical Practice Guidelines for Vascular Adequacy. *Am J Kidney Dis* 1997; 30 (supplement 3).
10. Health Care Financing Administration. *1994 Core Indicators Project Initial Results. Opportunities to Improve Care for Adult In-Center Hemodialysis Patients.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December 1994.
11. Health Care Financing Administration. *1995 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December 1995.
12. Health Care Financing Administration. *Highlights from the 1995 ESRD Core Indicators Project for Peritoneal Dialysis Patients.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, December 1995.
13. Health Care Financing Administration. *1996 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, Baltimore, Maryland, January 1997.
14. Health Care Financing Administration. *1997 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland, December 1997.
15. Health Care Financing Administration. *1998 Annual Report, End Stage Renal Disease Core Indicators Project.* Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland, December 1998.
16. Dean JA, Burton AH, Coulombier D, Breudel KA, Smith DC, Burton AH, Dicker RC, Sullivan K, Fagan RF, Arner TG. *Epi Info, Version 6.04a: a word processing, database, and statistics program for epidemiology on microcomputers.* Centers for Disease Control and Prevention, Atlanta, Georgia, U.S.A., 1996.

Appendix 8. (Continued)

17. Blagg CR, Liedtke RJ, Batjer JD, Racoosin B, Sawyer TK, Wick MJ, Lawson L, Wilkens K. Serum albumin concentration-related Health Care Financing Administration quality assurance criterion is method-dependent: revision is necessary. *Am J Kidney Dis* 1993;21:138-144.
18. U.S. Renal Data System, USRDS Annual Data Report, The National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 1999, Tables C.5 and C.6.
19. Norusis MJ. *SPSS for Windows Advance Statistics Release 8.0*. Chicago, IL, USA, 1997.
20. *A Guide For Improving the Quality of Care of Dialysis Patients; the National Anemia Cooperative Project*. US Department of Health and Human Services, Health Care Financing Administration, Baltimore, Maryland, July 1996.
21. Fraser CG, Wilkinson SP, Neville RG, Knox JD, King JC, MacWalter RS. Biologic variation of common hematologic laboratory quantities in the elderly. *J Clin Pathology* 1989;92:465-470.
22. Renal Physicians Association. Clinical practice guideline on adequacy of hemodialysis: Clinical practice guideline, number 1. December 1993. (pamphlet)
23. Daugirdas JT. Second generation logarithmic estimates of single-pool variable volume Kt/V: an analysis of error. *J Am Soc Nephrol* 1993; 4:1205-13.
24. Personal communication. Steve Schwab, MD, Duke University Medical Center, Durham, NC, Chair, NKF/DOQI Vascular Access Workgroup.
25. 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.
26. 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.

Appendix 9. List of Publications/Abstracts/Presentations of ESRD Core Indicators Data

Publications

1. Helgerson SD, McClellan WM, Frederick PR, Beaver SK, Frankenfield DL, McMullan M. Improvement in adequacy of delivered dialysis for adult in-center hemodialysis patients in the United States, 1993 to 1995. *Am J Kidney Dis* 1997;29:851-861.
2. Rocco MV, Flanigan MJ, Beaver S, Frederick P, Gentile DE, McClellan WM, Polder J, Prowant BF, Taylor L, Helgerson SD. Report From the 1995 Core Indicators for Peritoneal Dialysis Study Group. *Am J Kidney Dis* 1997;30:165-173.
3. Flanigan MJ, Rocco MV, Frankenfield DL, Bailie G, Frederick PR, Prowant BF, Taylor L. 1996 Peritoneal Dialysis-Core Indicators Report. *Am J Kidney Dis* 1998;32:1-9.
4. Frankenfield DL, McClellan WM, Helgerson SD, Lowrie EG, Rocco MV, Owen WF. Relationship between urea reduction ratio, demographic characteristics, and body weight for patients in the 1996 national ESRD Core Indicators Project. *Am J Kidney Dis* 1999;33:584-591.
5. Rocco MV, Flanigan MJ, Prowant B, Frederick P, Frankenfield DL. Cycler adequacy and prescription data in a national cohort sample: The 1997 ESRD Core Indicators Report. *Kidney Int* 1999;55:2030-2039.
6. Frankenfield DL, Prowant BF, Flanigan MJ, Frederick PR, Bailie GR, Helgerson SD, Rocco MV. Trends in clinical indicators of care for adult peritoneal dialysis patients in the U.S., 1995-1997. *Kidney Int* 1999;55:1998-2010.
7. Bailie GR, Frankenfield DL, Prowant BF, McClellan WM, Rocco MV. Erythropoietin use and hematocrit control in peritoneal dialysis patients. Report from the 1997 HCFA End-Stage Renal Disease Core Indicators Project. *Am J Kidney Dis* 1999;33:1187-1189.
8. Flanigan MJ, Rocco MV, Frankenfield D. Core Indicators Study—Anemia in peritoneal dialysis; Implications for future monitoring. *Seminars in Dialysis* 1999; 12:157-161.
9. Owen WF Jr., Szczech L, Johnson C, Frankenfield D. National perspective on iron therapy as a clinical performance measure for maintenance hemodialysis patients. *Am J Kidney Dis* 1999;34 (Suppl 2):S5-S11.
10. Frankenfield DL, Rocco MV, Frederick PR, Pugh J, McClellan WM, Owen WF Jr. Racial/ethnic analysis of selected intermediate outcomes for hemodialysis patients: Results from the 1997 ESRD Core Indicators Project *Am J Kidney Dis* 1999;34:721-730.
11. McClellan WM, Frankenfield DL, Frederick PR, Flanders WD, Alfaro-Correa A, Rocco M, Helgerson SD. Can dialysis therapy be improved? A Report from the ESRD Core Indicators Project. *Am J Kidney Dis* 1999; 34:1075-1082
12. Frankenfield DL, Johnson CA, Wish JB, Rocco MV, Madore F, Owen WF Jr. Anemia management of adult hemodialysis patients in the US: Patterns of erythropoietin and iron administration: Results from the 1997 ESRD Core Indicators Project *Kidney Int* (in press).

Appendix 9. (Continued)

Abstracts

1. Frankenfield DL, Frederick PR. Epoetin alfa (EPO) Dosing Patterns for In-Center Hemodialysis Patients - a National and Regional Snapshot. *International Pharmaceutical Abstracts* 1996;33(21):2283.
2. Rocco M, Flanigan M, Frederick P, Gentile D, Helgerson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Serum Albumin and Dialysis Adequacy. *J Am Soc Nephrol* 1996;7 (September):1067A.
3. Flanigan M, Rocco M, Frederick P, Gentile D, Helgerson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. *J Am Soc Nephrol* 1996;7(September):990A.
4. Prowant BF, Taylor L, Frederick PR. Health Care Financing Administration (HCFA) 1995 Core Indicators for Peritoneal Dialysis. *ANNA Journal* 1997;24:196.
5. Bailie G, Frankenfield D, Frederick P, Rocco M, Prowant B, Flanigan M. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. *J Am Soc Nephrol* 1997;8(September):215A.
6. Rocco M, Flanigan M, Prowant B, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): CAPD Prescription and Adequacy Data. *J Am Soc Nephrol* 1997;8(September):289A.
7. Rocco M, Flanigan M, Prowant B, Bailie G, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Cycloer Prescription and Adequacy Data. *J Am Soc Nephrol* 1997;8(September):290A.
8. Frankenfield DL, Frederick PR. Comparison of Epoetin Alfa (EPO) Dosing Patterns for In-Center Hemodialysis and Peritoneal Dialysis Patients - the 1996 End Stage Renal Disease (ESRD) Core Indicators Project. *International Pharmaceutical Abstracts* 1997;34(21):2212.
9. Flanigan MJ, Bailie G, Frankenfield D, Frederick P, Prowant B, Rocco M for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Albumin (Alb) and Nitrogen Appearance (nPCR) Data. *J Am Soc Nephrol* 1997;8:192A.
10. Bailie GR, Frankenfield DL, Frederick P, Prowant BR, McClellan W, Rocco MV, Flanigan M. Epo Use and Hct Control in Peritoneal Dialysis (PD) patients,: Report from the 1997 ESRD Core Indicators Project (CIP). *J Am Soc Nephrol* 1998;9(September): 139A.
11. Wish JB, Frankenfield DL, Frederick PR, Owen WF, Johnson CA, Rocco MV. Iron Management and Hematocrit Control in Hemodialysis Patients. Report from the 1997 HCFA Core Indicators Project. *J Am Soc Nephrol* 1998;9 (September):230A.
12. Flanigan M, Rocco MV, Frankenfield D, Bailie G, Frederick P, Prowant B, Taylor L for the PD-CIS Workgroup. 1997 ESRD Core Indicators Study for Peritoneal Dialysis (PD-CIS). Nutritional Indicators. *J Am Soc Nephrol* 1998;9 (September):233A.
13. Rocco M, Frankenfield D, Frederick P, Flanigan, M, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Trends in Clinical Indicators of Care for Adult Peritoneal Dialysis Patients in the U.S. from 1995 to 1997, Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 1998;9 (September):301A.
14. Rocco M, Flanigan M, Frankenfield D, Frederick P, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Cycloer Adequacy and Prescription Data in a National Cohort Sample: The 1997 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 1998;9 (September): 301A.

Appendix 9. (Continued)

15. Frankenfield DL, Johnson CA, Bailie GR. Management of Anemia in End Stage Renal Disease (ESRD) Patients in the U.S.: Results from the 1997 ESRD Core Indicators Project. *International Pharmaceutical Abstracts* 1998; 35(21):2292.
16. Frederick PR, Frankenfield DL, Hall K. Changes in Practice Patterns following Quality Measurement Instrument. *Am J Kidney Dis* 1999;33:A25.
17. Frederick PR, Frankenfield DL. Gender Analysis of the 1998 ESRD Core Indicators Project Data. Proceedings from the National Institutes of Health NIDDK Women and Renal Disease Conference. 1999.
18. Frankenfield DL, Eggers PW, Greer JW, Rocco MV, Frederick PR, Owen WF. Comparison of Intermediate Outcomes for Fee-For-Service and HMO In-Center Hemodialysis Patients: Results from the 1998 ESRD Core Indicators Project. *J Am Soc Nephrol* 1999;10(September):163A.
19. Frankenfield DL, Rocco MV, Frederick PR, Owen WF. Adequacy of Dialysis for Adult (≥ 18 years) In-Center Hemodialysis Patients: Results from the 1998 ESRD Core Indicators Project. *J Am Soc Nephrol* 1999;10(September):164A.
20. Johnson CA, Frankenfield DL, Rocco MV, Wish JB. Continued Improvement in Anemia Management in Hemodialysis (HD) Patients: Report from the 1998 HCFA Core Indicators Project (CIP). *J Am Soc Nephrol* 1999;10(September):169A.
21. Flanigan MJ, Rocco M, Frankenfield D, Frederick P, Bailie G, Prowant B. Nutritional Status of Peritoneal Dialysis (PD) Patients: The 1998 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 1999;10(September):241A.
22. Moore LW, Cockram DB, Frankenfield D, Rocco M. Cluster Analysis may Separate Nutritional and Inflammatory Parameters: A Report from the HCFA Core Indicators Project. *J Am Soc Nephrol* 1999;10 (September):250A.
23. Rocco M, Frankenfield D, Flanigan M, Prowant B. Dose of Dialysis and Risk of Death in Peritoneal Dialysis Patients in the United States. *J Am Soc Nephrol* 1999;10 (September):255A.
24. Rocco, M, Flanigan M, Frankenfield D, Frederick P, Prowant B, Bailie G. CAPD Adequacy and Prescription Data in a National Cohort Sample: The 1998 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 1999;10 (September):337A.
25. Rocco M, Frankenfield DL, Flanigan M, Frederick P, Prowant B, Bailie G. Cycler Adequacy and Prescription Data in a National Cohort Sample: The 1998 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). *J Am Soc Nephrol* 1999; 10(September):337A.
26. Frankenfield DL, Johnson CA. Management of Anemia in End-Stage Renal Disease (ESRD) Patients in the US: Results from the 1998 ESRD Core Indicators Project. *International Pharmaceutical Abstracts* 1999;36(21) (November):2266.

Appendix 9. (Continued)

Presentations

1. Frankenfield DL, Frederick PR. Epoetin alfa (EPO) Dosing Patterns for In-Center Hemodialysis Patients - a National and Regional Snapshot. Poster presentation at the 31st Annual American Society of Health System Pharmacists Midyear Clinical Meeting, New Orleans, LA. 1996.
2. Rocco M, Flanigan M, Frederick P, Gentile D, Helgeson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Serum Albumin and Dialysis Adequacy. Poster Presentation at the 29th Annual Meeting of the American Society of Nephrology, New Orleans, LA. 1996.
3. Flanigan M, Rocco M, Frederick P, Gentile D, Helgeson S, Krisher J, McClellan W, Polder J, Prowant B, Taylor L. 1995 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. Poster Presentation at the 29th Annual Meeting of the American Society of Nephrology, New Orleans, LA. 1996.
4. Bailie G, Frankenfield D, Frederick P, Rocco M, Prowant B, Flanigan M. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Hematocrit and Blood Pressure Data. Oral presentation at the 30th Annual Meeting of the American Society of Nephrology, San Antonio, TX. 1997.
5. Rocco M, Flanigan M, Prowant B, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): CAPD Prescription and Adequacy Data. Poster presentation at the 30th Annual Meeting of the American Society of Nephrology, San Antonio, TX. 1997.
6. Rocco M, Flanigan M, Prowant B, Bailie G, Frankenfield D, Frederick P for the HCFA ESRD PD-CIS Workgroup. 1996 ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS): Cycler Prescription and Adequacy Data. Poster presentation at the 30th Annual Meeting of the American Society of Nephrology, San Antonio, TX. 1997.
7. Frankenfield DL, Frederick PR. Comparison of Epoetin Alfa (EPO) Dosing Patterns for In-Center Hemodialysis and Peritoneal Dialysis Patients - the 1996 End Stage Renal Disease (ESRD) Core Indicators Project. Poster presentation at the 32nd Annual American Society of Health System Pharmacists Midyear Clinical Meeting, Atlanta, GA. 1997.
8. Frederick PR, Frankenfield DL. ESRD Core Indicators Project - A Health Care Quality Improvement Program Project Focused on Improving Care for Hemodialysis Patients. Poster presentation at the Ninth Annual National Forum on Quality Improvement in Health Care, Orlando, FL. 1997.
9. Bailie GR, Frankenfield DL, Frederick P, Prowant BR, McClellan W, Rocco MV, Flanigan M. Epo Use and Hct Control in Peritoneal Dialysis (PD) patients.; Report from the 1997 ESRD Core Indicators Project (CIP). Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.
10. Wish JB, Frankenfield DL, Frederick PR, Owen WF, Johnson, CA, Rocco MV. Iron Management and Hematocrit Control in Hemodialysis Patients. Report from the 1997 HCFA Core Indicators Project. Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.
11. Flanigan M, Rocco MV, Frankenfield D, Bailie G, Frederick P, Prowant B, Taylor L for the PD-CIS Workgroup. 1997 ESRD Core Indicators Study for Peritoneal Dialysis (PD-CIS). Nutritional Indicators. Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.

Appendix 9. (Continued)

12. Rocco M, Frankenfield D, Frederick P, Flanigan, M, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Trends in Clinical Indicators of Care for Adult Peritoneal Dialysis Patients in the U.S. from 1995 to 1997, Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Oral and Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.
13. Rocco M, Flanigan M, Frankenfield D, Frederick P, Prowant B, Bailie G for the HCFA Core Indicators Workgroup. Cycloer Adequacy and Prescription Data in a National Cohort Sample: The 1997 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Poster presentation at the 31st Annual Meeting of the American Society of Nephrology, Philadelphia, PA. 1998.
14. Frankenfield DL, Johnson CA, Bailie GR. Management of Anemia in End Stage Renal Disease (ESRD) Patients in the U.S.: Results from the 1997 ESRD Core Indicators Project. Poster presentation at the 33rd Annual American Society of Health System Pharmacists Midyear Clinical Meeting, Las Vegas, NV. 1998 .
15. Frederick PR, Frankenfield DL, Hall K. Changes in Practice Patterns following Quality Measurement Instrument Poster presentation at the 8th Annual National Kidney Foundation Clinical Nephrology Meeting. Washington DC. 1999.
16. Frederick PR, Prowant BF, Russell KA. ESRD-DOQI Clinical Performance Measures. Oral presentation at the American Nephrology Nurses' Association 30th National Symposium. Baltimore, MD. 1999.
17. Frederick PR, Frankenfield DL. Gender Analysis of the 1998 ESRD Core Indicators Project Data. Poster presentation at the National Institutes of Health NIDDK Women and Renal Disease Conference. Bethesda, MD. 1999.
18. Frankenfield DL, Eggers PW, Greer JW, Rocco MV, Frederick PR, Owen WF. Comparison of Intermediate Outcomes for Fee-For-Service and HMO In-Center Hemodialysis Patients: Results from the 1998 ESRD Core Indicators Project. Poster presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
19. Frankenfield DL, Rocco MV, Frederick PR, Owen WF. Adequacy of Dialysis for Adult (≥ 18 years) In-Center Hemodialysis Patients: Results from the 1998 ESRD Core Indicators Project. Poster presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
20. Johnson CA, Frankenfield DL, Rocco MV, Wish JB. Continued Improvement in Anemia Management in Hemodialysis (HD) Patients: Report from the 1998 HCFA Core Indicators Project (CIP). Oral presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
21. Flanigan MJ, Rocco M, Frankenfield D, Frederick P, Bailie G, Prowant B. Nutritional Status of Peritoneal Dialysis (PD) Patients: The 1998 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Oral presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
22. Moore LW, Cockram DB, Frankenfield D, Rocco M. Cluster Analysis may Separate Nutritional and Inflammatory Parameters: A Report from the HCFA Core Indicators Project. Poster presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
23. Rocco M, Frankenfield D, Flanigan M, Prowant B. Dose of Dialysis and Risk of Death in Peritoneal Dialysis Patients in the United States. Poster presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.

Appendix 9. (Continued)

24. Rocco M, Flanigan M, Frankenfield D, Frederick P, Prowant B, Bailie G. CAPD Adequacy and Prescription Data in a National Cohort Sample: The 1998 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Oral presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
25. Rocco M, Frankenfield D, Flanigan M, Frederick P, Prowant B, Bailie G. Cycloer Adequacy and Prescription Data in a National Cohort Sample: The 1998 Health Care Financing Administration (HCFA) ESRD Peritoneal Dialysis Core Indicators Study (PD-CIS). Poster Presentation at the 32nd Annual Meeting of the American Society of Nephrology. Miami, FL. 1999.
26. Frankenfield DL, Johnson CA. Management of Anemia in End-Stage Renal Disease (ESRD) Patients in the US: Results from the 1998 ESRD Core Indicators Project. Poster presentation at the 34th Annual American Society of Health System Pharmacists Midyear Clinical Meeting, Orlando, FL. 1999.

