

# 2004 ANNUAL REPORT ESRD CLINICAL PERFORMANCE MEASURES PROJECT

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

DECEMBER 2004



Department of Health and Human Services  
Centers for Medicare & Medicaid Services  
Office of Clinical Standards & Quality  
Baltimore, Maryland



Data on adult in-center hemodialysis patients are from October–December 2003

Data on adult peritoneal dialysis patients are from October 2003–March 2004

Data on pediatric in-center hemodialysis patients are from October–December 2003

Suggested citation for this Report is as follows:

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Note: The clinical data collected for the 2004 ESRD Clinical Performance Measures Project were from the time period of October–December 2003 for the in-center hemodialysis patients and October 2003–March 2004 for the adult peritoneal dialysis patients.

#### **2005 Data Collection Effort**

In 2005, we will again collect data for the ESRD Clinical Performance Measures on a national sample of adult in-center hemodialysis, adult peritoneal dialysis, and all pediatric in-center hemodialysis 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 4 & 5).

Look for this Report, as well as other ESRD Clinical Performance Measures Project and Core Indicators Project Reports, on the Internet at: [www.cms.hhs.gov/esrd/1.asp](http://www.cms.hhs.gov/esrd/1.asp).

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- The many other individuals in the renal community and CMS who contributed to this work.

## ACRONYMS

### List of Commonly Used Acronyms

<b>AM</b> Anemia Management	<b>Hgb</b> Hemoglobin
<b>AV</b> Arterio Venous	<b>IV</b> Intravenous
<b>AVF</b> Arteriovenous Fistula	<b>K/DOQI</b> Kidney Disease Outcomes Quality Initiative
<b>BCG</b> Bromcresol Green Laboratory Method	<b>Kt/V or Kt/V<sub>urea</sub></b> Urea Clearance x Time/the Volume of Distribution of Urea (fractional clearance of urea)
<b>BCP</b> Bromcresol Purple Laboratory Method	<b>KUf</b> Ultrafiltration Coefficient
<b>BMI</b> Body Mass Index	<b>LDO</b> Large Dialysis Organization
<b>BSA</b> Body Surface Area	<b>NIPD</b> Nightly Intermittent Peritoneal Dialysis
<b>BUN</b> Blood Urea Nitrogen	<b>NKF</b> National Kidney Foundation
<b>CAPD</b> Continuous Ambulatory Peritoneal Dialysis	<b>PET</b> Peritoneal Equilibration Test
<b>CCPD</b> Continuous Cycling Peritoneal Dialysis	<b>PD</b> Peritoneal Dialysis
<b>CI</b> Confidence Interval	<b>QA</b> Quality Assurance
<b>CIP</b> Core Indicators Project	<b>QI</b> Quality Improvement
<b>CMS</b> Centers for Medicare & Medicaid Services	<b>RRF</b> Residual Renal Function
<b>CPM</b> Clinical Performance Measure	<b>SC</b> Subcutaneous
<b>CQI</b> Continuous Quality Improvement	<b>SD</b> Standard Deviation
<b>CrCl</b> Creatinine Clearance	<b>SIMS</b> Standard Information Management System
<b>CSC</b> Computer Sciences Corporation	<b>SI Units</b> Système International Units
<b>DM</b> Diabetes Mellitus	<b>SLE</b> Systemic Lupus Erythematosus
<b>DOQI</b> Dialysis Outcomes Quality Initiative	<b>spKt/V</b> Single-Pool Kt/V
<b>D/P Cr Ratio</b> Dialysate/Plasma Creatinine Ratio	<b>TCV</b> Total Cell Volume
<b>ESRD</b> End-Stage Renal Disease	<b>TSAT</b> Transferrin Saturation
<b>FSGS</b> Focal and Segmental Glomerulosclerosis	<b>UKM</b> Urea Kinetic Modeling
<b>GFR</b> Glomerular Filtration Rate	<b>URR</b> Urea Reduction Ratio
<b>HCFA</b> Health Care Financing Administration	<b>USRDS</b> United States Renal Data System
<b>HCQIP</b> Health Care Quality Improvement Program	<b>VA</b> Vascular Access
<b>HD</b> Hemodialysis	

## I. INTRODUCTION

The ESRD Clinical Performance Measures (CPM) Project, now in its eleventh year, is a national effort led by the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), and its eighteen ESRD Networks to assist dialysis providers to improve patient care and outcomes. Since 1994 the Project has documented continued improvements, specifically in the areas of adequacy of dialysis and anemia management. The providers of dialysis services are to be commended for their ongoing efforts to improve patient care.

The 2004 ESRD CPM Annual Report describes the findings of several important clinical measures and/or characteristics of a nationally representative random sample of adult (aged  $\geq 18$  years) in-center hemodialysis patients and peritoneal dialysis patients. Included again this year are the findings for all in-center hemodialysis patients aged  $< 18$ .

The most recent data described in this Report are from the 2004 study period which includes the months of October-December 2003 for the in-center hemodialysis patients and October 2003-March 2004 for the peritoneal dialysis patients. This Report also compares the 2004 study period findings to findings from previous study periods AND it identifies opportunities to improve care for dialysis patients.

The full Report can be found on the Internet at [www.cms.hhs.gov/esrd/1.asp](http://www.cms.hhs.gov/esrd/1.asp). PowerPoint files containing all of the figures in this Report can also be found at this Internet site. Please feel free to use any of these slides in presentations and quality improvement activities.

This Report contains six major sections: **Background and Project Methods**, **Clinical Performance Measures (CPMs)**, **Other Significant Findings and Trends**, **Adult In-Center Hemodialysis Patients**, **Adult Peritoneal Dialysis Patients**, and **Pediatric In-Center Hemodialysis Patients** (aged  $< 18$ ). The lists of tables and figures have been moved to the back of the Report as Section IX (page 61).

This Report also contains some features or tools to assist dialysis providers in using the information from this project. Appendices 8 and 9 (pages 97 and 99) contain tear out CPM Outcomes Comparison Tools (one for hemodialysis and one for peritoneal dialysis) that providers can use to record their facility-specific results for comparisons to national and Network findings (Network rates are only available for hemodialysis). (Note: Each provider will have to calculate its own facility-specific results to record on this tool.) Even though the national and Network hemodialysis findings included in this Report are from the time period October – December 2003 (national peritoneal dialysis findings are from the time period October 2003 – March 2004), the facility data that you calculate and enter on this form can be from any time period. Appendix 7 provides you with some Network-level hemodialysis findings that you can use to record on your Network's Outcomes Comparison Tool (Appendix 8). On the back of each tool are two graphs that can be used to record monthly facility-specific adequacy and anemia manage-

ment results. We encourage each dialysis facility to use these tools. Consider posting the charts somewhere in the dialysis facility that is visible to staff and patients so everyone can follow the monthly entries.

The **Background and Project Methods** section beginning on page 6, provides information on the Medicare ESRD program and why the ESRD CPM Project was initiated. Patient selection criteria and data collection and analysis methodologies are also described.

The **Clinical Performance Measures (CPMs)** section beginning on page 11, has a short summary of each CPM collected for this project as well as a brief summary of the 2004 CPM findings. Appendix 1 (page 67) provides a more detailed description of each CPM.

The **Other Significant Findings and Trends** section beginning on page 15, provides highlights of important findings from the 2004 ESRD CPM Project.

The **Adult In-Center Hemodialysis Patients**, **Adult Peritoneal Dialysis Patients**, and the **Pediatric In-Center Hemodialysis Patients** sections describe the findings for each cohort for the 2004 study period and compare these findings to previous study periods.

This Report provides the dialysis community with an initial look at Network and national profiles for the clinical measures that were collected for the ESRD CPM Project. While significant improvements in care have occurred, the opportunities to improve care for dialysis patients in the U.S. in the areas of adequacy of dialysis, vascular access, and anemia management continue. Every dialysis caregiver should be familiar with the clinical practice guidelines developed by the Renal Physicians Association (1) and the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) (2, 3, 4, 5). Your Network staff and Medical Review Board are also available to assist you in identifying opportunities for improvement.

In the future, the ESRD Networks, in collaboration with dialysis facilities, will continue to assess the ESRD CPMs for dialysis patients in the U.S. The purpose of this effort will be to assess improvement in care and to encourage further improvements. The ultimate goal is to improve patient care and outcomes for all ESRD patients.

### 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. This project collects the serum albumin value as well as the test method, (bromocresol green [BCG] method and bromocresol purple [BCP] method), because 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 (6).

For the history of this project, mean serum albumin values < 3.5 g/dL (35 g/L) by the BCG method have been defined as an indicator of inadequate serum albumin. Since the percent of mean serum albumin values < 3.2 g/dL (32 g/L) by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 g/dL (35 g/L) by the BCG method, we have historically for the purpose of this report also defined a BCP result < 3.2 g/dL (32 g/L) as an indicator of inadequate serum albumin. In June 2000, the NKF-K/DOQI Guidelines for Nutrition in Chronic Renal Failure were published. Guideline 3 of the Clinical Practice Guidelines states that a pre-dialysis or stabilized serum albumin equal to or greater than the lower limit of normal range (approximately 4.0 g/dL [40 g/L] for the bromocresol green method) is the outcome goal (7).

Findings from this project allow us to report the percent of patients with mean serum albumin values  $\geq$  4.0 g/dL (40 g/L) (BCG method) or  $\geq$  3.7 g/dL (37 g/L) (BCP method) and the percent of patients with mean serum albumin values  $\geq$  3.5 g/dL (35 g/L) (BCG method) or  $\geq$  3.2 g/dL (32 g/L) (BCP method) for adult hemodialysis patients in each Network area and nationally, and nationally for adult peritoneal dialysis patients and pediatric hemodialysis patients.

### **Pediatric In-Center Hemodialysis Patients**

Although there are no CPMs established for the pediatric age group, demographic and clinical information from October-December 2003 were collected on all hemodialysis patients aged < 18 years in the U.S. in order to describe several core indicators of dialysis care. These core indicators included clearance, vascular access, anemia management, and serum albumin.

## **II. BACKGROUND AND PROJECT METHODS**

### **A. MEDICARE'S ESRD PROGRAM**

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 333 per million population (8). As of December 31, 2003, there were 310,095 patients receiving dialysis therapy in the United States (9).

### **ESRD Health Care Quality Improvement Program (HCQIP)**

The CMS, which oversees the Medicare program, contracts with 18 ESRD Network Organizations throughout the United States. The ESRD Networks stimulate and facilitate improvements in the quality of care for ESRD patients throughout the U.S. In 1994, CMS, 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 (10). This approach was named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP gives the ESRD Networks and CMS a chance to demonstrate that health care provided to Medicare beneficiaries with renal disease can be measurably improved. The HCQIP is based on the assumption that most health care providers welcome information and, where necessary, help in applying the tools and techniques of quality management (11).

### **ESRD Core Indicators Project**

One activity included in the ESRD HCQIP was the National/Network ESRD Core Indicators Project (CIP). This project was initiated in 1994 as a national intervention approach to assist dialysis providers in the improvement of patient care and outcomes. The ESRD CIP was CMS's first nationwide population-based project designed to assess and identify opportunities to improve the care of patients with ESRD (12). 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. The ESRD CIP was merged with the ESRD Clinical Performance Measures Project in 1999.

## ESRD Clinical Performance Measures Project

Section 4558(b) of the Balanced Budget Act (BBA) of 1997 required CMS 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, CMS funded the development of Clinical Performance Measures (CPMs) based on the National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI) Clinical Practice Guidelines (13, 14, 15, 16).

For information regarding the development of the CPMs, refer to the 1999 Annual Report, End-Stage Renal Disease Clinical Performance Measures Project on the Internet at [www.cms.hhs.gov/esrd/1.asp](http://www.cms.hhs.gov/esrd/1.asp).

On March 1, 1999, the ESRD CIP 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.

This 2004 ESRD CPM Project Annual Report provides the results of the CPMs on a sample of adult in-center hemodialysis patients and adult peritoneal dialysis patients. Findings on all pediatric (aged < 18 years) in-center hemodialysis patients are also included. The Report does not provide results on a dialysis facility-specific basis. The quality of dialysis services is reported for adult and pediatric in-center hemodialysis patients for the last quarter in 2003 and adult peritoneal dialysis patients for the time period October 2003–March 2004.

CMS 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 by identifying opportunities for improvement. One of these tools includes data feedback reports based on the clinical information obtained from the ESRD CPM Project. We invite the renal community to provide us with ideas and feedback as to ways CMS and the Networks can best help the community to improve patient care.

## B. 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 dialysis patients. 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 (17). From 1994 to 1998, CMS collected ESRD data under the ESRD CIP. The purpose of these data collections was to determine whether patterns in these clinical measures had changed and if opportunities to improve care continued to exist (18–22).

The initial data collection effort for the ESRD CPMs was conducted in 1999. This effort examined data from October–December 1998 for adult in-center hemodialysis patients, and from October 1998 to March 1999 for adult peritoneal dialysis patients. Information to calculate the CPMs was collected and further opportunities to improve care were identified (23).

This Report describes the findings from the sixth data collection effort for the ESRD CPMs which was conducted in 2004. Data were collected from October–December 2003 for adult and pediatric in-center hemodialysis patients, and from October 2003–March 2004 for adult peritoneal dialysis patients. These data help to determine if there are opportunities to improve care and to evaluate patterns of care across the nation.

## 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 2004, a listing of adult (aged  $\geq 18$  years as of September 30, 2003) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 2003, was obtained from each of the 18 ESRD Networks.

From this universe of patients, a national random sample, stratified by Network, of adult in-center hemodialysis patients was drawn. The sample size of adult in-center hemodialysis patients was selected to allow estimation of a proportion with a 95% confidence interval (CI) around that estimate no larger than 10 percentage points (i.e.,  $\pm 5\%$ ) for Network-specific estimates of the key Hemodialysis CPMs and other indicators. Additionally, a 30% over-sample was drawn to compensate for an anticipated non-response rate and to assure a large enough sample of the adult in-center hemodialysis patient population who were dialyzing at least six months prior to October 1, 2003. The final sample consisted of 8,881 adult in-center hemodialysis patients.

The peritoneal dialysis patient sample included a random selection of 5% of adult peritoneal dialysis patients in the nation. Additionally, a 10% over-sample was drawn to compensate for an anticipated non-response rate. The final sample consisted of 1,453 peritoneal dialysis patients.

All pediatric (aged < 18 years) in-center hemodialysis patients in the U.S. ( $n = 809$ ) were included in the 2004 ESRD CPM Study.

## C. SAMPLE SELECTION

### Data Collection

Two data collection forms were used: a four-page in-center hemodialysis form and a four-page peritoneal dialysis form (Appendices 2, 3); the use of these forms was authorized through the National Institutes of Health (NIH) clinical exemption process. Descriptive information on each selected patient and dialysis facility was printed onto gummed labels, and sent to the individual ESRD Networks along with the forms to be used to collect the data. 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.

For the first time this study year, electronic data were accepted from the large dialysis organizations (LDOs) (Fresenius Medical Care N.A., Dialysis Clinic, Inc. Renal Care Group, Inc., Gambro Healthcare/USA, and National Nephrology Associates). As there had been no prior validation of the quality of electronic data from the LDOs, the electronically submitted data were entered onto paper forms, and these paper forms were sent to facilities with one or more sampled patients. Facility staff had the opportunity to review the data provided on the paper form and make changes/corrections if needed. These updated paper collection forms were then forwarded to the appropriate Network, where data were reviewed for acceptability and manually entered into the Network database using the Standard Information Management System (SIMS).

Facilities that were not part of an LDO (non-LDO facilities) with one or more patients in the samples received a blank paper data collection form as in past study years. Clinical information contained in the medical record was abstracted for each patient in the adult hemodialysis sample and for all pediatric in-center hemodialysis patients who received in-center hemodialysis at anytime during October, November, and December 2003. Clinical information contained in the medical records was also abstracted for each patient in the adult peritoneal dialysis sample who was receiving peritoneal dialysis at any time during the two-month periods of October-November 2003, December 2003-January 2004, and February-March 2004. The completed data collection forms were then forwarded to the appropriate Network, where data were reviewed for acceptability and manually entered into SIMS.

In August 2004, each Network sent a copy of their VISION data files to CMS's contractor, Computer Sciences Corporation (CSC) where the data were aggregated and then submitted to CMS for data analysis.

### Adult In-Center Hemodialysis

Initial analyses for the CPMs and other indicators focused on the following elements: paired pre- and post-dialysis BUN values with patient height and weight and dialysis session length (used to calculate spKt/V values); hemoglobin 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, and at least one serum albumin. We were able to include for analysis 8,634 of the 8,881 patients from the sample (response rate = 97%) (TABLE 1). In the vascular access section, some findings are presented for incident patients (see definition of incident patients, Table 8 page 26) alone. Other findings in this section are presented for prevalent or all patients, which includes incident patients.

Characteristics regarding the gender, race, ethnicity, age, diagnosis, and duration of dialysis (years) 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 (8). Data regarding Epoetin use,

serum ferritin concentrations, transferrin saturation, iron use, dialyzer KUf (ultrafiltration coefficient, the permeability of a dialyzer membrane to water), and actual time on dialysis were also analyzed. The initial analysis utilized SAS v.8.02 and Statistical Package for the Social Sciences (SPSS) software (24, 25).

**TABLE 1:** Number of adult in-center hemodialysis patients in each Network in December 2003, sample size and response rate for the 2004 ESRD CPM Project.

Network	# HD Patients Dec 2003	Sample Size	# Acceptable Forms <sup>^</sup>	Response Rate %
1	9,433	487	475	97.5
2	20,301	497	485	97.6
3	12,025	491	488	99.4
4	12,909	493	479	97.2
5	16,665	495	482	97.4
6	26,214	501	487	97.2
7	16,282	495	476	96.2
8	15,645	495	482	97.4
9	19,652	497	490	98.6
10	11,551	491	461	93.9
11	16,869	496	475	95.8
12	10,157	488	442	90.6
13	11,921	491	488	99.4
14	23,721	499	487	97.6
15	12,130	491	482	98.2
16	6,880	481	478	99.4
17	14,257	494	482	97.6
18	21,980	499	495	99.2
<b>Total</b>	<b>278,592</b>	<b>8,881</b>	<b>8,634</b>	<b>97.2</b>

<sup>^</sup> 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 2003 for the following items: 1) 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 96% of patients for hemoglobin and 96% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 91% 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 95%. Monthly paired pre- and post-dialysis BUN values were available for 84% of patients.

**TABLE 2:** Characteristics of adult in-center hemodialysis patients in the 2004 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 2002.

Patient Characteristic	2004 CPM Sample for Analysis		All US in 2002*	
	# ^	%	# in 1,000s	%
<b>TOTAL</b>	<b>8,634</b>	<b>100</b>	<b>280.4</b>	<b>100</b>
<b>GENDER</b>				
Men	4,601	53	150.7	54
Women	4,033	47	129.6	46
<b>RACE</b>				
American Indian/ Alaska Native	164	2	4.1	1
Asian/Pacific Islander	363	4	10.8	4
Black	3,086	36	106.2	38
White	4,769	55	153.8	55
Other/Unknown	252	3	5.4	2
<b>ETHNICITY</b>				
Hispanic	1,120	13	37.6	13
Non-Hispanic	7,359	85	242.7	87
Unknown	155	2	0	0
<b>AGE GROUP (years)</b>				
18-49	2,031	24	63.5 **	23
50-59	1,739	20	55.7	20
60-64	944	11	31.4	11
65-69	1,031	12	33.5	12
70-79	1,908	22	64.2	23
80+	981	11	30.8	11
<b>CAUSE of ESRD</b>				
Diabetes mellitus	3,650	42	117.8	42
Hypertension	2,413	28	78.9	28
Glomerulonephritis	834	10	30.6	11
Other/Unknown	1,737	20	53.0	19
<b>DURATION of DIALYSIS (years)</b>				
<0.5	1,082	13		
0.5-0.9	1,070	12		
1.0-1.9	1,688	20		
2.0-2.9	1,194	14		
3.0-3.9	933	11		
4.0+	2,645	31		

\*USRDS: 2004 Annual Data Report, Bethesda, MD, National Institutes of Health, 2004. Table D.5

^ Subgroup totals may not equal 8,634 due to missing data.

\*\* For ages 20-49 years

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

For this Report, each patient’s mean value for the three-month project period was determined from the available data for the following items: spKt/V (calculated using the Daugirdas II formula [26]), dialysis session length, dialyzer KUf, blood pump flow rates, hemoglobin, transferrin saturation, serum ferritin concentration, prescribed Epoetin or Darbepoetin dose and serum albumin. Information on prescription, route of iron administration as well as dose of intravenous (IV) iron was collected. Because we had data from a stratified random sample of patients (i.e., a separate random sample from each of the 18 Networks), 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.

### Adult Peritoneal Dialysis

The initial analysis focused on the adequacy of peritoneal 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 2003–March 2004. Of the 1,453 patients sampled, 1,377 patients were included in the sample for analysis (95% response rate) (TABLE 3). Selected patient character-

**TABLE 3:** Number of adult peritoneal dialysis patients in each Network in December 2003, sample size and response rate for the 2004 ESRD CPM Project.

Network	#			
	Peritoneal Dialysis Patients in December 2003	Sample Size	# Acceptable Forms^	Response Rate %
1	1,171	72	69	95.8
2	1,255	61	60	98.4
3	1,031	52	52	100.0
4	927	39	37	94.9
5	1,568	92	78	84.8
6	2,415	150	138	92.0
7	1,321	72	68	94.4
8	1,676	94	93	98.9
9	2,153	122	116	95.1
10	1,167	61	58	95.1
11	1,700	98	94	95.9
12	1,259	66	57	86.4
13	1,099	45	45	100.0
14	1,947	100	100	100.0
15	1,128	54	53	98.1
16	943	62	61	98.4
17	1,641	92	88	95.7
18	2,017	121	110	90.9
<b>Total</b>	<b>26,418</b>	<b>1,453</b>	<b>1,377</b>	<b>94.8</b>

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

**TABLE 4:** Characteristics of adult peritoneal dialysis patients in the 2004 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 2002.

Patient Characteristic	2004 CPM Sample for Analysis		All US in 2002*	
	# ^	%	# in 1,000s	%
<b>TOTAL</b>	<b>1,377</b>	<b>100</b>	<b>24.9</b>	<b>100</b>
<b>GENDER</b>				
Men	709	51	12.8	51
Women	668	49	12.1	49
<b>RACE</b>				
American Indian/ Alaska Native	15	1	0.3	1.2
Asian/Pacific Islander	80	6	1.3	5
Black	353	26	6.4	26
White	880	64	16.4	66
Other/Unknown	49	4	0.5	2
<b>ETHNICITY</b>				
Hispanic	173	13	3.2	13
Non-Hispanic	1,189	86	21.7	87
Other/Unknown	15	1	0	0
<b>AGE GROUP (years)</b>				
18-49	501	36	8.3**	33
50-59	330	24	5.6	22
60-64	142	10	2.6	10
65-69	143	10	2.6	10
70-79	206	15	3.8	15
80+	55	4	1.2	5
<b>CAUSE of ESRD</b>				
Diabetes mellitus	489	36	8.8	35
Hypertension	329	24	5.6	22
Glomerulonephritis	206	15	4.5	18
Other/Unknown	353	26	6.0	24
<b>DURATION of DIALYSIS (years)</b>				
<0.5	181	13		
0.5-0.9	208	15		
1.0-1.9	335	24		
2.0+	201	15		
3.0-3.9	145	11		
4.0	303	22		

\*USRDS: 2004 Annual Data Report, Bethesda, MD, National Institutes of Health, 2004. Table D.5

^ Subgroup totals may not equal 1,377 due to missing data.

\*\* For ages 20-49 years

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

istics of this sample for analysis were similar to the characteristics of the overall U.S. peritoneal dialysis population (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<sub>urea</sub>, weekly creatinine clearance, hemoglobin, serum albumin, prescribed Epoetin or Darbepoetin dose, serum ferritin concentration, and transferrin saturation. Information on iron prescription and route of administration, as well as dose of IV iron was collected. The data are from a random sample, not stratified by Network; thus, only national aggregate data are reported. No Network-specific or facility-specific analyses were conducted.

### Pediatric In-Center Hemodialysis Patients

Inclusion of a pediatric record for analysis required that data were 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, and at least one serum albumin. Of the 809 pediatric patients, 678 patients were included in the sample for analysis (84% response rate). Selected patient characteristics of this sample for analysis are shown in Table 5.

For this Report, each patient's mean value for the three-month project period was determined from the available data for the following items: spKt/V, dialysis session length, dialyzer KUf, blood pump flow rates, hemoglobin, transferrin saturation, serum ferritin concentration, prescribed Epoetin dose and route of administration, and serum albumin. Information on iron prescription and route of iron administration, as well as dose of IV iron was collected. The data were collected on all pediatric patients aged < 18 years in the U.S. Only national aggregate data are reported. No Network-specific or facility-specific analyses were conducted.

### D. REPORT FORMAT

This Report describes the clinical performance measures and other findings for both the adult in-center hemodialysis patient sample and the adult peritoneal dialysis patient sample in separate sections, V and VI, respectively, for the following study periods: October–December 2003 for the adult in-center hemodialysis patients, and October 2003–March 2004 for the adult peritoneal dialysis patients. This report also describes findings on clinical parameters of care for pediatric in-center hemodialysis patients in the U.S. for October-December 2003 in Section VII.

The national results are presented separately in tables by gender, race, ethnicity, age group (for adult patients: 18-44, 45-54, 55-64, 65-74, and 75+ years of age, for pediatric patients: 0-4, 5-9, 10-14, and 15 to < 18 years of age), diagnosis of ESRD, and duration of dialysis. The diagnoses are categorized as diabetes mellitus, hypertension, glomerulonephritis, and other/unknown for adult patients. 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 2004 CPM study period are compared to key findings from previous study periods.

**TABLE 5:** Characteristics of pediatric (aged < 18 years) in-center hemodialysis patients in the 2004 ESRD CPM Project.

Patient Characteristic	2004 CPM Project	
	#^	%
<b>TOTAL</b>	<b>678</b>	<b>100</b>
<b>GENDER</b>		
Males	384	57
Females	294	43
<b>RACE</b>		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	20	3
Black	244	36
White	357	53
Other/Unknown	48	7
<b>ETHNICITY</b>		
Hispanic	217	32
Non-Hispanic	456	67
Other/Unknown	5	1
<b>AGE GROUP (years)</b>		
0-4	28	4
5-9	63	9
10-14	235	35
15 to <18	352	52
<b>CAUSE of ESRD</b>		
Congenital/Urologic	188	28
Glomerulonephritis	96	14
FSGS	91	13
SLE	33	5
Cystic Disease	24	4
Hypertension	24	4
Other/Unknown	222	33
<b>DURATION of DIALYSIS (years)</b>		
<0.5	142	21
0.5-0.9	133	20
1.0-1.9	118	17
2.0-2.9	75	11
3.0-3.9	40	6
4.0+	166	24

^Subgroup totals may not equal 678 due to missing data.

\*Data not displayed, n < 11.

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

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 2003 for the following items: 1) 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 93% of patients for hemoglobin and 92% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 85% 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 91%. Monthly paired pre- and post-dialysis BUN values were available for 78% of patients.

### III. CLINICAL PERFORMANCE MEASURES (CPMs)

The clinical information abstracted by facility staff is used in this Report to describe some of the CPMs that were developed from the NKF-DOQI Guidelines and other quality indicators for several aspects of care for adult dialysis patients. These CPMs do not apply to patients under the age of 18 years. The CPMs were developed in the areas of hemodialysis and peritoneal dialysis adequacy, vascular access and anemia management. A complete description of the 13 CPMs appears in Appendix 1.

#### The Hemodialysis Adequacy CPMs described in this report are:

**CPM I.** The patient's delivered dose of hemodialysis is measured at least once per month.

**CPM 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 spKt/V.

**CPM III.** The patient's (for those patients on hemodialysis six months or longer and dialyzing three times per week) delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month study period) of hemodialysis is spKt/V  $\geq$  1.2.

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

#### The Peritoneal Dialysis Adequacy CPMs described in this report are:

**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).

**CPM II.** The patient's total solute clearance for urea (weekly Kt/V<sub>urea</sub>) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 1).

**CPM III.** For patients on continuous ambulatory peritoneal dialysis (CAPD), the delivered peritoneal dialysis dose is a total Kt/V<sub>urea</sub> of at least 2.0 per week and a total creatinine clearance (CrCl) of at least 60 L/week/1.73 m<sup>2</sup> OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For CCPD patients (cycler patients with a daytime dwell), the weekly delivered peritoneal dialysis dose is a total Kt/V<sub>urea</sub> of at least 2.1 and a weekly total creatinine clearance of at least 63L/week/1.73 m<sup>2</sup> OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For NIPD patients (cycler patients without a daytime dwell), the weekly delivered peritoneal dialysis dose is a total  $Kt/V_{\text{urea}}$  of at least 2.2 and a weekly total creatinine clearance of at least 66 L/week/1.73 m<sup>2</sup>. OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

### The Vascular Access CPMs described in this Report are:

**CPM I.** A primary arteriovenous 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 prevalent patients undergoing hemodialysis.

**CPM II.** Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters continuously for  $\geq 90$  days as their permanent chronic dialysis access.

**CPM III.** A patient's AV graft should be routinely monitored for stenosis. (See Vascular Access CPM III in Appendix 1 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:

**CPM I.** The target hemoglobin for patients prescribed Epoetin is 11- 12 g/dL (110-120 g/L). Patients with a mean hemoglobin  $> 12$  g/dL (120 g/L) and not prescribed Epoetin were excluded from analysis for this CPM.

**CPM Iia.** For anemic patients (hemoglobin  $< 11$  g/dL (110 g/L) in at least one study month) or patients prescribed Epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) at least once in a three-month period for hemodialysis patients and at least two times during the six-month study period for peritoneal dialysis patients.

**CPM Iib.** For anemic patients (hemoglobin  $< 11$  g/dL (110 g/L) in at least one study month) or patients prescribed Epoetin, at least one serum ferritin concentration  $\geq 100$  ng/mL and at least one transferrin saturation  $\geq 20\%$  were documented during the three-month study period for hemodialysis patients or during the six-month study period for peritoneal dialysis patients.

**CPM III.** All anemic patients (hemoglobin  $< 11$  g/dL (110 g/L) in at least one study month) 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 IV iron; UNLESS the mean transferrin saturation was  $\geq 50\%$  or the mean serum ferritin concentration was  $\geq 800$  ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed oral iron.

The clinical information collected to calculate these CPMs allows us to describe other aspects of anemia management (or indicators). For example, the percents of patients with a mean hemoglobin  $\geq 11$  g/dL (110 g/L) and  $< 10$  g/dL (100 g/L) are

profiled in this Report. Additionally, the percents of all patients with mean transferrin saturation  $\geq 20\%$ , mean serum ferritin concentration  $\geq 100$  ng/mL, and the percents of patients prescribed subcutaneous (SC) Epoetin or IV iron are profiled.

Information was collected on Darbepoetin prescription and dose and on IV iron doses again during this data collection period. All monthly recorded data were used in determining the percent of patients prescribed Epoetin or Darbepoetin. A "held" dose of Epoetin was entered as "zero" units. A "held" dose of Darbepoetin was entered as "zero" micrograms. These zero values were included in the calculation of the mean weekly Epoetin or Darbepoetin doses. The average prescribed weekly Epoetin doses (units/kg/week) were stratified by hemoglobin values.

All monthly recorded data were used in determining the percent of patients prescribed any IV iron product. The average administered dose of IV iron (mg/month) was stratified by hemoglobin values.

The CPMs may have been calculated slightly differently than other findings reported in this Annual Report. Please refer to Appendix 1 for the specific inclusion and exclusion criteria for each CPM.

NOTE: Highlights of important findings from the 2004 ESRD CPM Project may be found on the following pages:

CPM highlights for adult hemodialysis patients, page 13

CPM highlights for adult peritoneal dialysis patients, page 14

Significant findings for adult in-center hemodialysis patients, page 18

Significant findings for adult peritoneal dialysis patients, page 19

Significant findings for pediatric in-center hemodialysis patients, page 20

These highlights are available on the Internet at [www.cms.hhs.gov/esrd/1.asp](http://www.cms.hhs.gov/esrd/1.asp).

### 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, Black, White, and Other/Unknown. In the figures, these clinical characteristics are compared by race group; however, the comparisons are limited to White vs. Black. The reason for this is sample size. Because of small sample size (TABLE 2), the 95% confidence intervals for estimates for American Indian/Alaska Native, Asian/Pacific Islander, etc. race groups are very broad. On the other hand, the sample size for White and Black patients was large enough to provide stable estimates; i.e., the 95% confidence intervals are narrow.

**CPM HIGHLIGHTS FROM THE NATIONAL 2004 ESRD PROJECT**

**Random Sample of Adult In-Center Hemodialysis (HD) Patients (n=8,634 sample for analysis)  
The data are from OCT-DEC 2003:**

**HD Adequacy**

- 83% of patients had monthly adequacy measurements performed (HD Adequacy CPM I)
- 83% of patients had their delivered spKt/V calculated using either UKM or the Daugirdas II formula (26) (HD Adequacy CPM II)
- 94% of patients on dialysis for 6 months or more and dialyzing three times a week had a mean delivered adequacy dose of spKt/V  $\geq 1.2$  calculated using the Daugirdas II formula (HD Adequacy CPM III)

**Vascular Access (VA)**

- 35% of incident patients were dialyzed using an AV fistula (AVF) (VA CPM I) (FIGURE 30)
- 35% of prevalent patients were dialyzed using an AVF (VA CPM I) (FIGURES 2, 30)
- 20% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer (VA CPM II) (FIGURE 2)

- 77% of prevalent patients with an AV graft were routinely monitored for the presence of stenosis (VA CPM III)

**Anemia Management (AM)**

- 36% of targeted patients prescribed Epoetin had a mean hemoglobin 11.0-12.0 g/dL (110-120 g/L) (AM CPM I)
- 96% of patients who met the inclusion criteria<sup>1</sup> had at least one documented transferrin saturation value and one documented serum ferritin concentration value during the study period (AM CPM IIa)
- 81% of patients who met the inclusion criteria<sup>1</sup> had at least one transferrin saturation  $\geq 20\%$  and one serum ferritin concentration  $\geq 100$  ng/mL during the study period (AM CPM IIb)
- 79% of patients who met the inclusion criteria<sup>1</sup> were prescribed intravenous iron in at least one month during the study period (AM CPM III)

<sup>1</sup>See Appendix 1 for a description of the inclusion and exclusion criteria.

ESRD CPM Trends (percent of patients meeting the CPMs) <sup>1</sup>	Year					
	1998	1999	2000	2001	2002	2003
<b>HD Adequacy</b>						
HD Adequacy CPM I (monthly measurement of delivered HD dose)	79	76	80	82	83	<b>83</b>
HD Adequacy CPM II (method of measurement of delivered HD dose)	99	50	52	68	67	<b>83</b>
HD Adequacy CPM III (mean delivered HD dose $\geq 1.2$ )	85	90	91	92	92	<b>94</b>
<b>Vascular Access</b>						
Vascular Access CPM Ia (incident patients with an AVF <sup>2</sup> as access)	26	28	27	29	27	<b>35</b>
Vascular Access CPM Ib (prevalent patients with an AVF as access)	26	27	30	31	33	<b>35</b>
Vascular Access CPM II (dialyzed with a chronic catheter <sup>3</sup> )	14	14	17	19	21	<b>20</b>
Vascular Access CPM III (AV graft was routinely monitored for stenosis)	37	45	47	51	61	<b>77</b>
<b>Anemia Management</b>						
Anemia CPM I (mean Hgb 11-12 g/dL)	36	36	38	38	36	<b>36</b>
Anemia CPM IIa (iron stores assessed for anemic patients or patients prescribed Epoetin)	90	89	91	92	94	<b>96</b>
Anemia CPM IIb (iron stores maintained at K/DOQI targets)	67	66	71	75	78	<b>81</b>
Anemia CPM III (administration of IV iron to anemic patients)	63	67	73	77	79	<b>79</b>

<sup>1</sup> See Appendix 1 for a description of the inclusion and exclusion criteria.

<sup>2</sup> arteriovenous fistula

<sup>3</sup> for 90 days or longer

NOTE: Please note that when a single year such as 2003 is used in displaying data, it refers to October, November, and December of that year for the hemodialysis patients.

## CPM HIGHLIGHTS FROM THE NATIONAL 2004 ESRD PROJECT

### Random Sample of Adult Peritoneal Dialysis (PD) Patients (n=1,377 sample for analysis) The data are from OCT 2003–MAR 2004:

#### PD Adequacy

- 86% of patients had at least one measured total solute clearance for urea and creatinine (PD Adequacy CPM I) during the six-month study period (FIGURE 3)
- 44% of patients had their total solute clearance for urea and creatinine calculated in a standard way<sup>1</sup> (PD Adequacy CPM II) (FIGURE 3)
- 70% of CAPD patients had a mean weekly  $Kt/V_{urea}$  of  $\geq 2.0$  and a mean weekly creatinine clearance  $\geq 60$  L/week/1.73m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (PD Adequacy CPM III) (FIGURES 4, 52)
- 65% of Cycler patients with a daytime dwell had a mean weekly  $Kt/V_{urea}$  of  $\geq 2.1$  and a mean weekly creatinine clearance  $\geq 63$  L/week/1.73m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (PD Adequacy CPM III) (FIGURES 4, 52)
- 62% of Cycler patients without a daytime dwell had a mean  $Kt/V_{urea}$  of  $\geq 2.2$  and a mean weekly creatinine clearance

$\geq 66$  L/week/1.73m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (PD Adequacy CPM III) (FIGURES 4, 52)

#### Anemia Management (AM)

- 39% of targeted patients prescribed Epoetin had a mean hemoglobin between 11.0-12.0 g/dL (110-120 g/L) (AM CPM I)
- 79% of patients who met the inclusion criteria<sup>2</sup> for this CPM had at least two documented transferrin saturation values and two documented serum ferritin concentration values during the six-month study period (AM CPM IIa)
- 83% of patients who met the inclusion criteria<sup>2</sup> for this CPM had at least one transferrin saturation  $\geq 20\%$  and one serum ferritin concentration  $\geq 100$  ng/mL during the six-month study period (AM CPM IIb)
- 29% of patients who met the inclusion criteria<sup>2</sup> for this CPM were prescribed intravenous iron in at least one of the two-month periods during the six-month study period (AM CPM III)

<sup>1</sup> See Appendix 1 for a description of standard ways for calculating total solute clearance.

<sup>2</sup> See Appendix 1 for a description of the inclusion and exclusion criteria.

Using the 1997 NKF-DOQI guidelines (14):

For CAPD patients: weekly  $Kt/V_{urea} \geq 2.0$ ; weekly CrCl  $\geq 60$  L/week/1.73m<sup>2</sup>

For cycler patients with daytime dwell (CCPD patients): weekly  $Kt/V_{urea} \geq 2.1$ ; weekly CrCl  $\geq 63$  L/week/1.73m<sup>2</sup>

For nighttime cycler patients (NIPD patients) (no daytime dwell): weekly  $Kt/V_{urea} \geq 2.2$ ; weekly CrCl  $\geq 66$  L/week/1.73m<sup>2</sup>

ESRD CPM Trends (percent of patients meeting the CPMs) <sup>1</sup>	Year					
	1999	2000	2001	2002	2003	2004
<b>PD Adequacy</b>						
PD Adequacy CPM I (measurement of total solute clearance at regular intervals)	82	83	85	86	88	<b>86</b>
PD Adequacy CPM II (weekly $Kt/V_{urea}$ & weekly CrCl calculated in a standard way) <sup>2</sup>	55	59	62	62	65	<b>44</b>
PD Adequacy CPM III (delivered PD dose meets K/DOQI thresholds)						
CAPD	55	68	69	68	71	<b>70</b>
Cycler with daytime dwell	58	65	62	70	66	<b>65</b>
Cycler without daytime dwell	45	66	64	61	67	<b>62</b>
<b>Anemia Management</b>						
Anemia CPM I (mean Hgb 11-12 g/dL)	32	34	39	36	39	<b>39</b>
Anemia CPM IIa (iron stores assessed for anemic patients or patients prescribed Epoetin)	70	68	72	74	77	<b>79</b>
Anemia CPM IIb (iron stores maintained at K/DOQI targets)	72	70	75	76	81	<b>83</b>
Anemia CPM III (administration of IV iron to anemic patients)	17	18	23	31	32	<b>29</b>

<sup>1</sup> See Appendix 1 for a description of the inclusion and exclusion criteria.

<sup>2</sup> See Appendix 1 for a description of standard ways for calculating total solute clearance.

NOTE: When a single year, such as 2004, is used for the peritoneal dialysis patients, it refers to January, February, and March of that year as well as October, November, and December of the previous year.

**IV. OTHER SIGNIFICANT FINDINGS AND TRENDS**

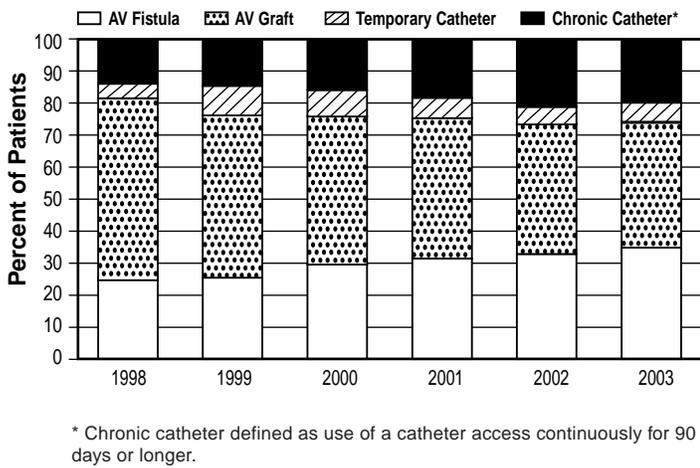
**ESRD CPM Data Trends**

The figures on the following pages show the trends in the ESRD CPM data for various study periods.

Please note that when a single year such as 2003 is used in displaying data, it refers to October, November, and December of that year for the hemodialysis patients. When a single year, such as 2004, is used for the peritoneal dialysis patients, it refers to January, February, and March of that year as well as October, November, and December of the previous year. Also, "adult" refers to ages  $\geq 18$  years and "pediatric" refers to ages  $< 18$  years.

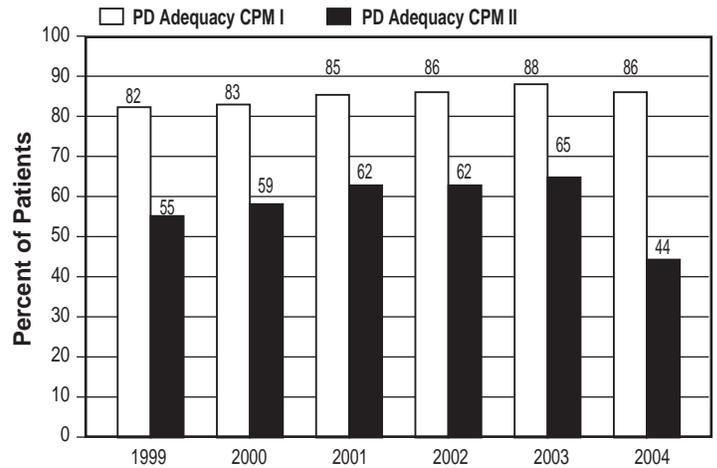
**Vascular Access Trends**

**Figure 2:** Vascular access type for all adult in-center hemodialysis patients on their last hemodialysis session during the study period. 2004 ESRD CPM Project.



**Peritoneal Dialysis Adequacy Trends**

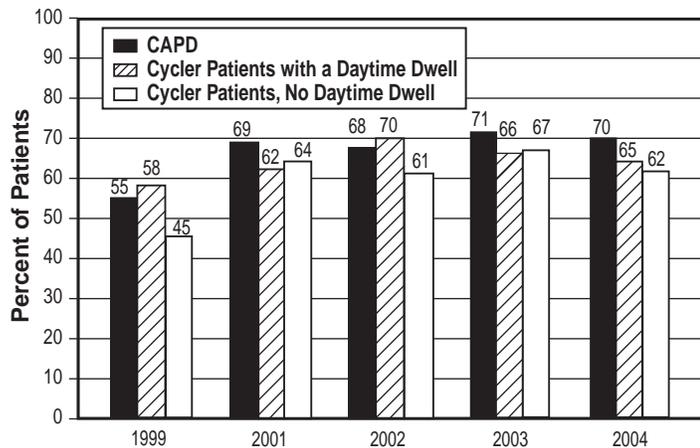
**Figure 3:** Percent of adult peritoneal dialysis patients with total solute clearance for urea and creatinine measured at least once during the study period (PD Adequacy CPM I) and with total solute clearance calculated in a standard way\* (PD Adequacy CPM II), October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.



\*See Appendix 1 for a complete description of the standard methods to calculate the solute clearance for urea and creatinine.

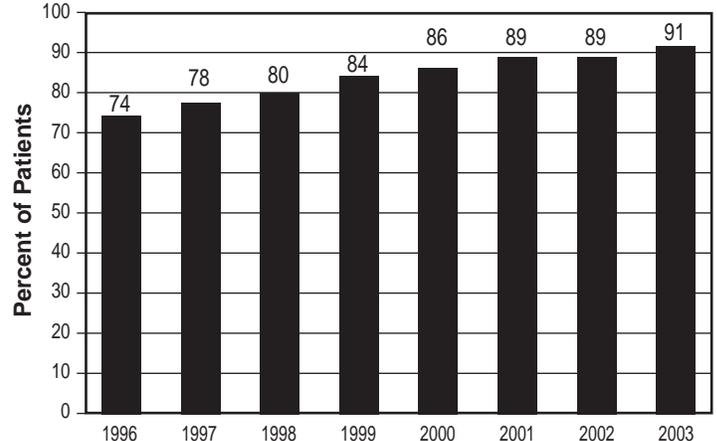
**Peritoneal Dialysis Adequacy Trends**

**Figure 4:** Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly  $Kt/V_{urea}$  and weekly creatinine clearance (PD Adequacy CPM III). 2004 ESRD CPM Project.



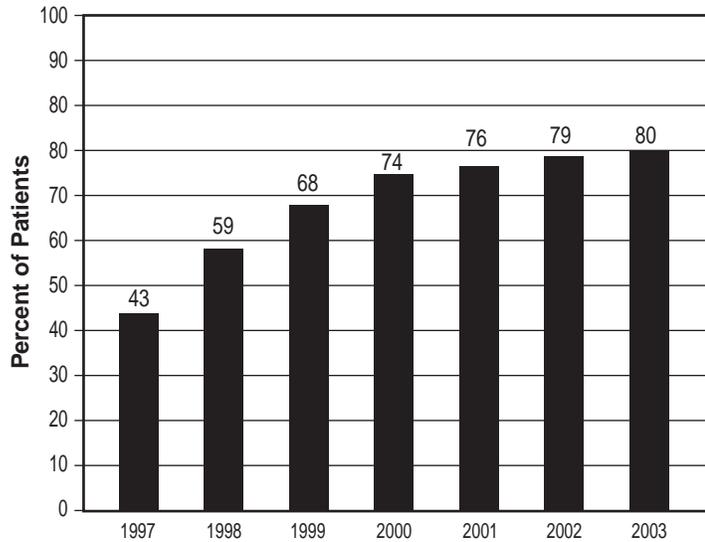
**Hemodialysis Adequacy Trends**

**Figure 5:** Percent of adult in-center hemodialysis patients with mean delivered calculated, single session single pool (sp)Kt/V  $\geq 1.2$  in October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



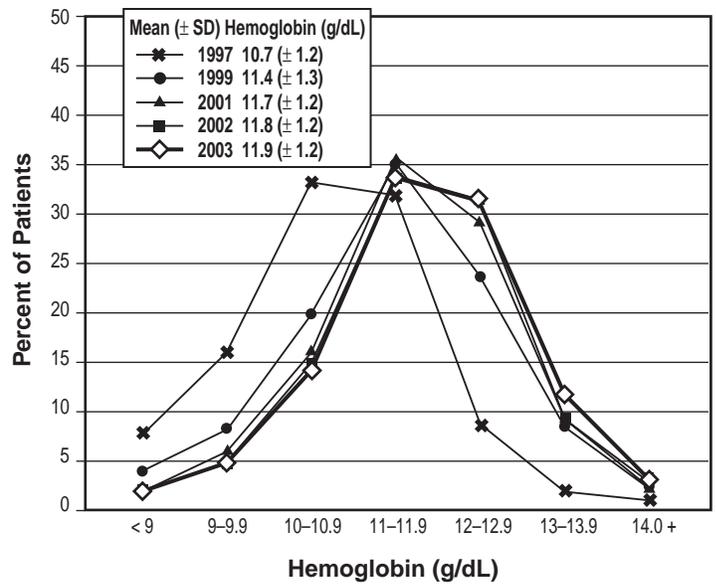
**Anemia Management Trends**

**Figure 6:** Percent of adult in-center hemodialysis patients with mean hemoglobin  $\geq 11$  g/dL, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



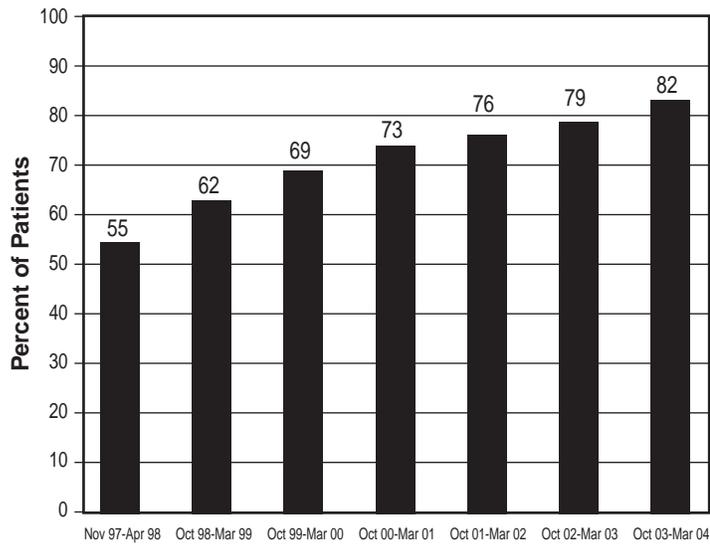
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 7:** Distribution of mean hemoglobin values for adult in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



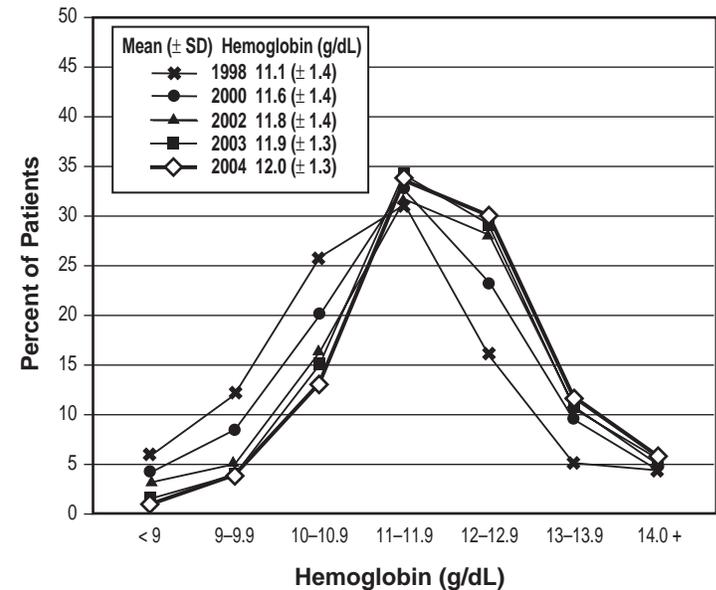
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 8:** Percent of adult peritoneal dialysis patients with mean hemoglobin  $\geq 11$  g/dL, October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

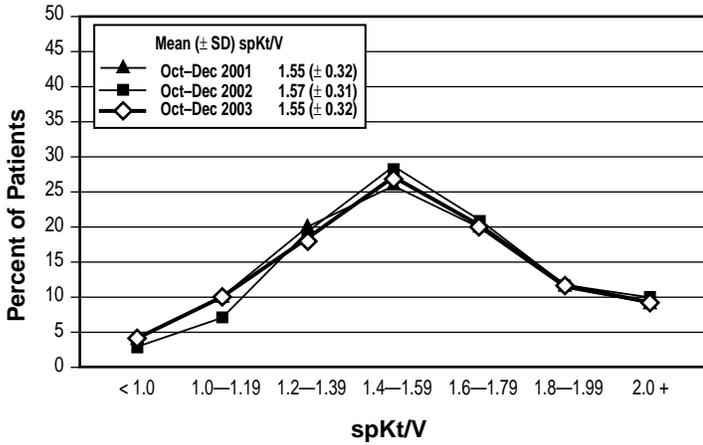
**Figure 9:** Distribution of mean hemoglobin values for adult peritoneal dialysis patients, October 2003-March 2004 compared to previous study periods. 2004 ESRD CPM Project.



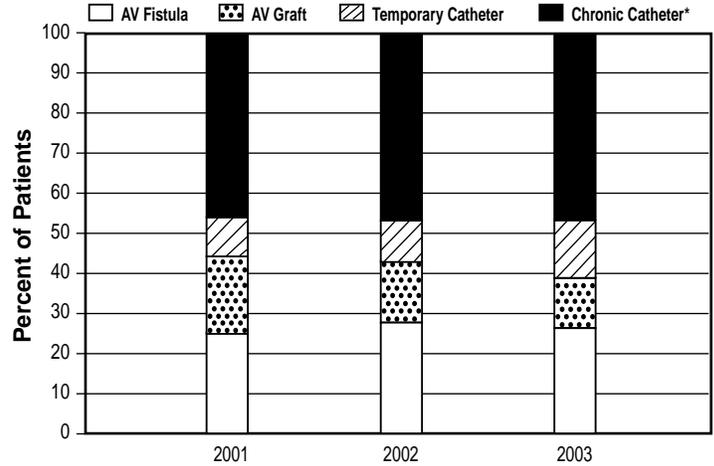
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Pediatric Dialysis Trends**

**Figure 10:** Distribution of mean delivered calculated, single session spKt/V values for pediatric (aged < 18 years) in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.

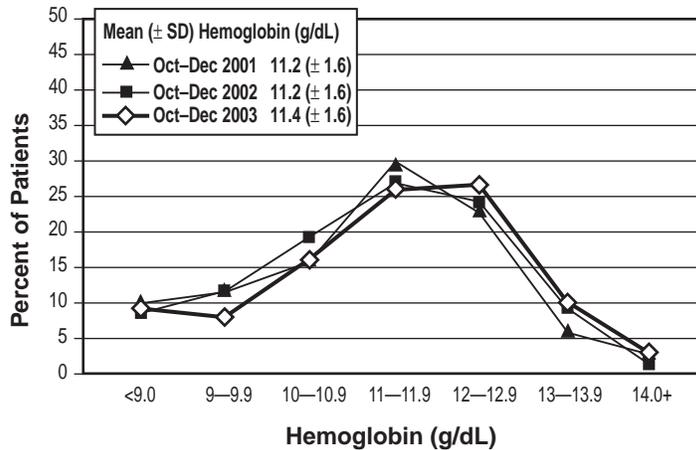


**Figure 11:** Vascular access type for pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period. 2004 ESRD CPM Project.



\*Chronic catheter use defined as continuous catheter use 90 days or longer.

**Figure 12:** Distribution of mean hemoglobin values for pediatric (aged < 18 years) in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

## SIGNIFICANT FINDINGS FROM THE NATIONAL 2004 ESRD CPM PROJECT

### Random Sample of Adult In-Center Hemodialysis (HD) Patients (n=8,634 sample for analysis) The data are from OCT-DEC 2003:

#### HD Adequacy

- 91% of prevalent patients had a mean delivered calculated, single session adequacy dose of  $\text{spKt/V} \geq 1.2$  (FIGURE 5)
- 94% of female patients and 88% of male patients were receiving dialysis with a mean delivered calculated, single session  $\text{spKt/V} \geq 1.2$  in OCT-DEC 2003 (TABLE 6)
- Mean ( $\pm$  SD)  $\text{spKt/V}$  was 1.53 ( $\pm$  0.26)
- 87% of patients had a mean URR  $\geq 65\%$
- Mean ( $\pm$  SD) URR was 72.0 ( $\pm$  6.8)%
- Mean ( $\pm$  SD) dialysis session length was 216 ( $\pm$  30) minutes (FIGURE 20)

#### Opportunity to Improve Adequacy

- 9% of patients did not have a mean  $\text{spKt/V} \geq 1.2$  during the three-month study period

#### Vascular Access

- 35% of incident and 35% of prevalent patients were dialyzed with an AVF during their last hemodialysis session OCT-DEC 2003 (TABLE 8)
- 75% of patients with an AVF or AV graft had their access routinely monitored for the presence of stenosis during the three-month study period

#### Opportunities to Improve Vascular Access

- 65% of incident patients and 65% of all patients were not dialyzed with an AVF during their last hemodialysis session OCT-DEC 2003
- 23% of patients with an AV graft did not have this graft routinely monitored for the presence of stenosis during the three-month study period

#### Anemia Management (AM)

- 80% of patients had a mean hemoglobin  $\geq 11$  g/dL (110 g/L) in the last quarter of 2003 (FIGURE 6)
- 6% of patients had a mean hemoglobin  $< 10.0$  g/dL (100 g/L) (FIGURE 32, TABLE 12)

- Mean ( $\pm$  SD) hemoglobin was 11.9 ( $\pm$  1.2) g/dL (119 [ $\pm$  12] g/L) (FIGURES 7, 32, TABLE 12)
- Mean ( $\pm$  SD) weekly IV and SC Epoetin dose was 271.3 ( $\pm$  251.8) units/kg/week and 206.2 ( $\pm$  184.8) units/kg/week respectively (FIGURE 39)
- 81% of patients had a mean transferrin saturation  $\geq 20\%$  (FIGURE 40, TABLE 14)
- 94% of patients had a mean serum ferritin concentration  $\geq 100$  ng/mL (FIGURE 40, TABLE 14)
- 25% of patients had a mean serum ferritin  $> 800$  ng/mL (FIGURE 40, TABLE 14)
- 65% of patients were prescribed IV iron during the study period (TABLE 14)
- Mean ( $\pm$  SD) IV iron dose was 233.4 ( $\pm$  194.4) mg/month (FIGURE 37)

#### Opportunities to Improve Anemia Management

- 20% of patients did not have a mean hemoglobin  $\geq 11$  g/dL (110 g/L) during the three-month study period
- 19% of patients did not have a mean transferrin saturation  $\geq 20\%$  and 6% of patients did not have a mean serum ferritin  $\geq 100$  ng/mL
- 35% of patients were not prescribed IV iron during the study period

#### Serum Albumin

- 39% of patients had a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP)<sup>1</sup> (FIGURE 44, TABLE 15)
- 81% of patients had a mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) (FIGURE 44, TABLE 15)
- Mean ( $\pm$  SD) serum albumin was 3.8 ( $\pm$  0.4)/3.5 ( $\pm$  0.5) g/dL (38[ $\pm$ 4]/35[ $\pm$ 5] g/L) (BCG/BCP)

#### Opportunity to Improve Serum Albumin

- 61% of patients did not have a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) during the three-month study period

<sup>1</sup> BCG = bromcresol green, BCP = bromcresol purple; these are two different laboratory methods for assaying serum albumin.

**SIGNIFICANT FINDINGS FROM THE NATIONAL 2004 ESRD PROJECT****Random Sample of Adult Peritoneal Dialysis (PD) Patients (n=1,377 sample for analysis)  
The data are from OCT 2003–MAR 2004:****PD Adequacy**

- Mean weekly  $Kt/V_{\text{urea}}$  for CAPD patients was 2.28 ( $\pm 0.64$ )
- Mean weekly  $Kt/V_{\text{urea}}$  for Cycler patients with a daytime dwell was 2.29 ( $\pm 0.60$ ) (TABLE 18)
- Mean weekly  $Kt/V_{\text{urea}}$  for cycler patients without a daytime dwell was 2.39 ( $\pm 0.73$ ) (TABLE 18)

**Opportunities to Improve Adequacy**

- The adequacy of dialysis was not assessed during the 2003 study period for 14% of the sampled peritoneal dialysis patients
- 33% of CAPD patients did not achieve an adequate weekly  $Kt/V_{\text{urea}}$  and 34% did not achieve an adequate weekly CrCl. Likewise, 41% of cycler patients with a daytime dwell did not achieve an adequate weekly  $Kt/V_{\text{urea}}$  and 52% did not achieve an adequate weekly CrCl (TABLE 18)

**Anemia Management (AM)**

- 82% of patients had a mean hemoglobin  $\geq 11$  g/dL (FIGURES 8, 54)
- 85% of patients had a mean transferrin saturation  $\geq 20\%$  (FIGURE 56)
- 88% of patients had a mean serum ferritin concentration  $\geq 100$  ng/mL (FIGURE 56)
- Mean ( $\pm$  SD) hemoglobin was 12.0 ( $\pm 1.3$ ) g/dL (120 [ $\pm 13$ ] g/L) (FIGURES 9, 53, TABLE 19)

- The mean ( $\pm$  SD) SC and IV Epoetin doses were 155.7 ( $\pm 163.7$ ) and 177.5 ( $\pm 150.1$ ) units/kg/week, respectively (FIGURE 55)
- 15% of patients had a mean serum ferritin  $> 800$  ng/mL (FIGURE 56)

**Opportunities to Improve Anemia Management**

- 18% of patients did not have a mean hemoglobin  $\geq 11$  g/dL (110 g/L) in the 2003 study period
- 15% of patients did not have a mean transferrin saturation  $\geq 20\%$  and 12% of patients did not have a mean serum ferritin  $\geq 100$  ng/mL

**Serum Albumin**

- 20% of patients had a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP)<sup>1</sup> (FIGURE 57, TABLE 20)
- 63% of patients had a mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) (FIGURE 57, TABLE 20)
- Mean ( $\pm$  SD) serum albumin was 3.6 ( $\pm 0.5$ )/3.3 ( $\pm 0.5$ ) g/dL (36 [ $\pm 5$ ]/33 [ $\pm 5$ ] g/L) (BCG/BCP)

**Opportunities to Improve Serum Albumin**

- 80% of PD patients did not have mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) during the six-month study period
- 37% of PD patients did not have mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) during the six-month study period

<sup>1</sup>BCG = bromocresol green, BCP = bromocresol purple; these are two different laboratory methods for assaying serum albumin.

Using the 1997 NKF-DOQI guidelines (14):

For CAPD patients: weekly  $Kt/V_{\text{urea}} \geq 2.0$ ; weekly CrCl  $\geq 60$  L/week/1.73m<sup>2</sup>

For cycler patients with daytime dwell (CCPD patients): weekly  $Kt/V_{\text{urea}} \geq 2.1$ ; weekly CrCl  $\geq 63$  L/week/1.73m<sup>2</sup>

For nighttime cycler patients (NIPD patients) (no daytime dwell): weekly  $Kt/V_{\text{urea}} \geq 2.2$ ; weekly CrCl  $\geq 66$  L/week/1.73m<sup>2</sup>

## SIGNIFICANT FINDINGS FROM THE NATIONAL 2004 ESRD PROJECT

### 100% Sample Pediatric In-Center Hemodialysis Patients (HD) (aged < 18) (n=678 sample for analysis)

The data are from OCT–DEC 2003:

#### Clearance

- 86% of patients had a mean delivered calculated, single session adequacy dose of  $\text{spKt/V} \geq 1.2$  calculated using the Daugirdas II formula (26) (TABLE 21)
- Mean ( $\pm$  SD)  $\text{spKt/V}$  was 1.55 ( $\pm$  0.32) (FIGURES 10, 58)
- Mean ( $\pm$  SD) dialysis session length was 204 ( $\pm$  31) minutes

#### Opportunity to Improve Clearance

- 14% of patients did not have a mean  $\text{spKt/V} \geq 1.2$  during the three-month study period

#### Vascular Access

- 27% of patients were dialyzed using an AV fistula (AVF) (FIGURE 11, TABLE 22)
- 47% of patients were dialyzed with a chronic catheter continuously for 90 days or longer (FIGURE 11)
- 52% of patients with an AVF or an AV graft were routinely monitored for the presence of stenosis

#### Opportunity to Improve Vascular Access

- 48% of patients with an AVF or AV graft did not have this access routinely monitored for the presence of stenosis during the three-month study period

#### Anemia Management

- 67% of patients had a mean hemoglobin  $\geq 11$  g/dL (110 g/L) (FIGURE 67)

- Mean ( $\pm$  SD) hemoglobin was 11.4 ( $\pm$  1.6) g/dL (114 [ $\pm$  16]) g/L (FIGURES 12, 66, TABLE 24)
- Mean ( $\pm$  SD) weekly IV Epoetin dose was 368.6 ( $\pm$ 353.6) units/kg/week
- 73% of patients had a mean transferrin saturation  $\geq 20\%$
- 78% of patients had a mean serum ferritin concentration  $\geq 100$  ng/mL
- 13% of patients had a mean serum ferritin  $> 800$  ng/mL

#### Opportunity to Improve Anemia Management

- 33% of patients did not have a mean hemoglobin  $\geq 11$  g/dL (110 g/L) during the three-month study period

#### Serum Albumin

- 48% of patients had a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP)<sup>1</sup> (FIGURE 75, TABLE 25)
- 81% of patients had a mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) (FIGURE 75, TABLE 25)
- Mean ( $\pm$  SD) serum albumin was 3.9( $\pm$  0.5)/3.6( $\pm$  0.4) g/dL (39 [ $\pm$  5]/36 [ $\pm$  4] g/L) (BCG/BCP)

#### Opportunity to Improve Serum Albumin

- 52% of patients did not have a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) during the three-month study period

<sup>1</sup> BCG = bromcresol green, BCP = bromcresol purple; these are two different laboratory methods for assaying serum albumin.

### 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.

As you review this Report, 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.

## V. ADULT IN-CENTER HEMODIALYSIS PATIENTS

This section describes the findings for the sampled adult in-center hemodialysis patients for selected CPMs and other quality indicators related to adequacy of dialysis, vascular access, anemia management and serum albumin. Each of these subsections is further broken down into three parts:

- (1) national findings for selected CPMs for October–December 2003 (the serum albumin information is not considered a CPM for this report);
- (2) a description of other quality indicators or data analyses for October–December 2003; and
- (3) a comparison of CPM and/or other quality indicators results or findings for October–December 2003 and previous study periods.

A national random sample of adult ( $\geq 18$  years) in-center hemodialysis patients, stratified by Network, who were alive on December 31, 2003, was selected ( $n=8,881$ ). 8,634 patients (97%) were included in the sample for analysis.

### A. ADEQUACY OF HEMODIALYSIS

#### 1. CPM Findings for October–December 2003

Data to assess three hemodialysis adequacy CPMs were collected in 2004. The time period from which these data were abstracted was October–December 2003. The results for these CPMs are included in this section of the report (Hemodialysis Adequacy CPMs I–III).

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

**FINDING:** 83% of adult in-center hemodialysis patients in the sample for analysis had documented measurements of hemodialysis adequacy (URR and/or spKt/V) for each month during the three-month study period (October–December 2003). These measurements were recorded in the patient's chart, not calculated from individual data points. An additional 12% of the patients in the sample for analysis had documented adequacy measurements for two out of the three months, and another five 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 spKt/V) (26).

**FINDING:** 83% of adult in-center hemodialysis patients in the sample for analysis had delivered hemodialysis doses reported as spKt/V calculated using formal 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 spKt/V  $\geq 1.2$  using the Daugirdas II for-

mula (26). This CPM is calculated on the subset of patients who had been on hemodialysis for six months or longer and who were dialyzing three times per week ( $n=6,536$ ).

**FINDING:** For the last quarter of 2003, 94% of the adult in-center hemodialysis patients who met the inclusion criteria (only those patients who had been on hemodialysis for six months or longer and who were dialyzing three times per week [ $n=6,536$ ]) had a mean delivered calculated, single session (hereafter referred to as delivered) hemodialysis dose of spKt/V  $\geq 1.2$ .

#### 2. Other Hemodialysis Adequacy Findings for October–December 2003

**NOTE:** The following findings apply to all adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis. Only 0.5% ( $n=44$ ) of patients were dialyzed more than three times per week over the study period; these patients were included in the following hemodialysis adequacy findings.

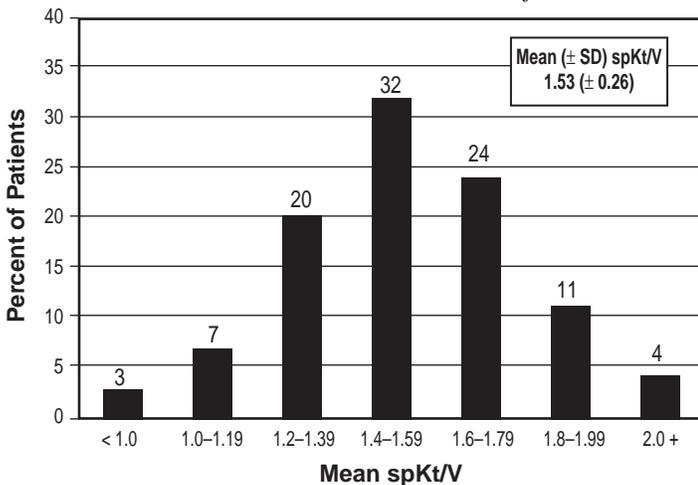
The mean ( $\pm$  SD) delivered calculated spKt/V of all adult in-center hemodialysis patients in the sample for analysis in the last quarter of 2003 was 1.53 ( $\pm 0.26$ ). The distribution of spKt/V values for these patients is shown in Figure 13. The mean ( $\pm$  SD) delivered calculated URR for this sample was 72.0 ( $\pm 6.8$ )%. 87% of patients had a mean delivered URR  $\geq 65$ %. The mean delivered spKt/V and the percent of patients with mean delivered spKt/V  $\geq 1.2$  and spKt/V  $\geq 1.3$  for gender, race, ethnicity, age, diagnosis, duration of dialysis, quintile of post-dialysis body weight, access type, and selected clinical parameters are shown in Table 6.

The percent of patients in the sample for analysis with at least one calculated spKt/V measure available ( $n=8,514$ ) who received adequate hemodialysis, defined as a mean delivered spKt/V  $\geq 1.2$ , approximately equivalent to URR  $\geq 65$ % (2) in the last quarter of 2003 was 91% (TABLE 6, FIGURE 5).

The percent of patients receiving hemodialysis with a mean delivered spKt/V  $\geq 1.2$  was higher for women than for men, higher for Whites, Native Americans/Alaska Natives, and Asians/Pacific Islanders than for Blacks, higher for Hispanics compared to non Hispanics, higher for patients dialyzing six months or longer than for patients dialyzing less than six months, higher for patients in lower quintiles of body weight, and higher for patients  $\geq 65$  years of age than for younger patients (TABLE 6).

A higher percent of patients with mean hemoglobin  $\geq 11$  g/dL (110 g/L) and mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) had a mean spKt/V  $\geq 1.2$  compared to patients with lower mean hemoglobin and serum albumin values. A higher percent of patients dialyzed with an AV fistula or an AV graft had a mean delivered spKt/V  $\geq 1.2$  compared to patients dialyzed with a catheter (93% and 95% vs. 82% respectively) (TABLE 6).

**Figure 13:** Distribution of mean delivered calculated, single session spKt/V values for adult in-center hemodialysis patients, October–December 2003. 2004 ESRD CPM Project.



The mean ( $\pm$  SD) dialysis session length was 216 ( $\pm$  30) minutes. The mean dialysis session length was somewhat longer for men than for women (224 minutes vs. 208 minutes), for Blacks than for Whites (222 minutes vs. 214 minutes), and for patients dialyzing six months or longer compared to patients dialyzing less than six months (217 minutes vs. 213 minutes). Patients in the highest quintile of post-dialysis body weight (kg) had longer dialysis session lengths compared to patients in the lowest quintile (237 minutes vs. 198 minutes). The mean dialysis session length was 219 minutes for patients dialyzed with an AVF, 214 minutes for patients with either a synthetic or bovine graft, and 216 minutes for patients with a catheter access during October-December 2003.

The mean ( $\pm$  SD) delivered blood pump flow rate 60 minutes into the dialysis session was 406 ( $\pm$  59) mL/min for patients with an AVF, 417 ( $\pm$  58) mL/min for patients with either a synthetic or bovine graft, and 350 ( $\pm$  55) mL/min for patients with a catheter access during October -December 2003 (FIGURE 14). Actual blood flow delivered to the dialyzer may be lower than the prescribed blood pump flow (27). The difference between prescribed and actual blood flow to the dialyzer increases with more negative pre-pump pressures. This is particularly true for catheters where differences of 25% or more may exist between delivered and prescribed blood flow to the dialyzer at prescribed blood pump flow rates of 400 mL/min or more (28).

**TABLE 6:** Mean delivered calculated, single session spKt/V and percent of adult in-center hemodialysis patients with mean delivered calculated, single session spKt/V  $\geq 1.2$  and  $\geq 1.3$  by patient characteristics, October-December 2003. 2004 ESRD CPM Project.

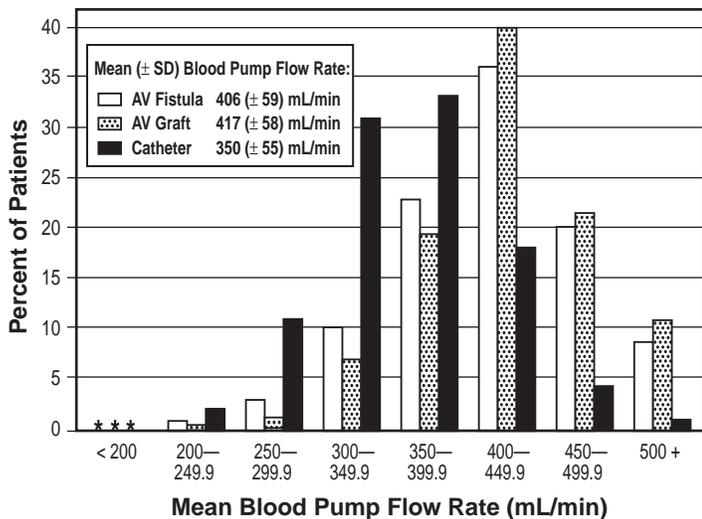
Patient Characteristics	Mean spKt/V	spKt/V $\geq 1.2$ %	spKt/V $\geq 1.3$ %
<b>TOTAL</b>	<b>1.53</b>	<b>91</b>	<b>83</b>
<b>GENDER</b>			
Men	1.47	88	78
Women	1.61	94	88
<b>RACE</b>			
American Indian/ Alaska Native	1.56	91	85
Asian/Pacific Islander	1.65	96	92
Black	1.50	90	80
White	1.55	91	84
Other/Unknown	1.55	88	82
<b>ETHNICITY</b>			
Hispanic	1.59	94	87
Non-Hispanic	1.53	90	82
<b>AGE GROUP (years)</b>			
18-44	1.50	87	78
45-54	1.49	88	79
55-64	1.51	90	81
65-74	1.56	93	87
75+	1.59	94	88
<b>CAUSE of ESRD</b>			
Diabetes mellitus	1.51	90	81
Hypertension	1.55	92	84
Glomerulonephritis	1.54	91	82
Other/Unknown	1.56	91	84
<b>DURATION of DIALYSIS (years)</b>			
< 0.5	1.40	75	63
0.5-0.9	1.47	86	73
1.0-1.9	1.54	93	85
2.0-2.9	1.56	94	87
3.0-3.9	1.57	95	91
4.0+	1.58	95	89
<b>QUINTILE POST-DIALYSIS BODY WEIGHT (kg)</b>			
32.0-58.9	1.71	97	94
59.0-68.4	1.59	95	89
68.5-77.9	1.53	92	85
78.0-91.6	1.47	89	79
91.7-209.3	1.39	81	67
<b>ACCESS TYPE</b>			
AV Fistula	1.54	93	85
AV Graft	1.59	95	90
Catheter	1.45	82	70
<b>MEAN Hgb (g/dL)</b>			
$\geq 11$	1.55	92	84
< 11	1.49	86	77
<b>MEAN SERUM ALBUMIN (g/dL)</b>			
$\geq 3.5/3.2$ BCG/BCP*	1.54	92	84
< 3.5/3.2 BCG/BCP	1.50	86	76

\* BCG/BCP = bromocresol green/bromocresol purple laboratory methods

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 14:** Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for adult in-center hemodialysis patients, by access type, October–December 2003. 2004 ESRD CPM Project.

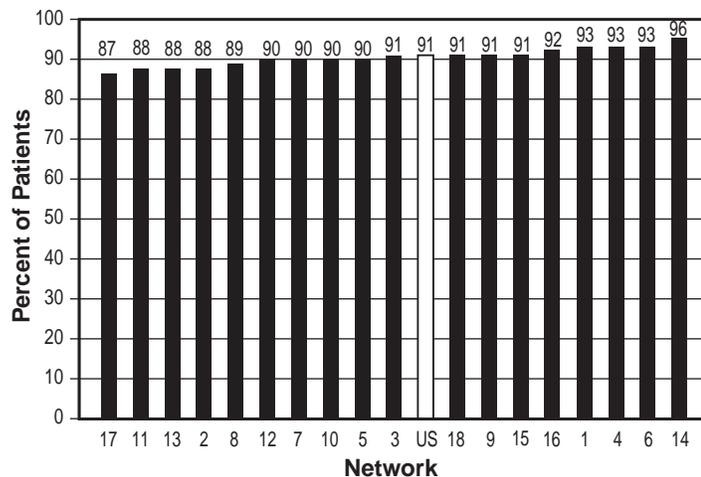


Note: Actual blood flow delivered to the dialyzer may be lower than the prescribed blood pump flow (27). This is particularly true for catheters where differences of 25% or more may exist between delivered and prescribed blood flow to the dialyzer at prescribed blood pump flow rates of 400 mL/min or more (28).

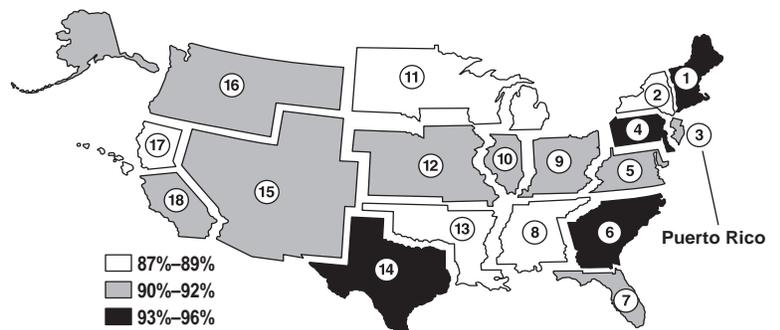
\*Value suppressed because n ≤ 10.

The percent of patients who received adequate hemodialysis varied significantly from one geographic region to another. Table 7 shows, by gender, race, and ethnicity, the percent of patients who received hemodialysis with a mean delivered spKt/V ≥ 1.2 in each Network area. The percent of all patients with mean delivered spKt/V ≥ 1.2 ranged from 87% to 96% among the 18 Networks (FIGURES 15, 16).

**Figure 15:** Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V ≥ 1.2, by Network, October–December 2003. 2004 ESRD CPM Project.



**Figure 16:** Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V ≥ 1.2, by Network, October–December 2003. 2004 ESRD CPM Project.

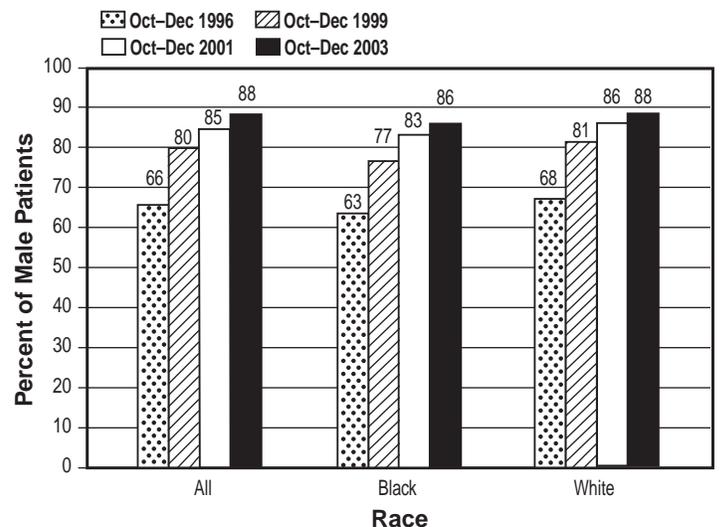


### 3. CPM and other Findings for October-December 2003 compared to previous study periods

Note: The following findings apply to all adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The mean (± SD) delivered spKt/V in October-December 2003 was 1.53 (± 0.26), an increase from previous study years. The percent of patients receiving dialysis with a mean delivered spKt/V ≥ 1.2 increased significantly from 86% in late 2000 to 91% in late 2003 (FIGURE 5, TABLE 6). This significant improvement occurred for both men and women and for White and Black patients (FIGURES 17, 18).

**Figure 17:** Percent of adult male in-center hemodialysis patients with mean delivered, single session spKt/V ≥ 1.2, by race, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.



**TABLE 7: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V  $\geq$  1.2, by gender, race, ethnicity, and Network, October-December 2003. 2004 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	93	88	91	93	90	93	90	89	91	90	88	90	88	96	91	92	87	91	91
GENDER																			
Men	91	85	89	91	89	90	84	86	88	86	85	85	82	93	89	89	84	88	88
Women	95	92	94	94	91	95	97	93	95	94	91	94	93	99	94	95	91	95	94
RACE																			
Black	95	89	92	90	86	93	91	90	89	88	86	93	86	94	85	89	84	91	90
White	92	88	91	94	97	93	89	87	93	90	89	88	89	97	91	92	84	90	91
ETHNICITY																			
Hispanic	91	93	88	100	*	*	95	*	*	94	100	93	*	97	95	88	93	92	94
Non-Hispanic	93	88	92	93	90	93	89	89	92	89	87	89	87	95	90	92	85	90	90

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

\* Value suppressed because  $n \leq 10$ .

**Figure 18:** Percent of adult female in-center hemodialysis patients with mean delivered, single session  $spKt/V \geq 1.2$ , by race, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.

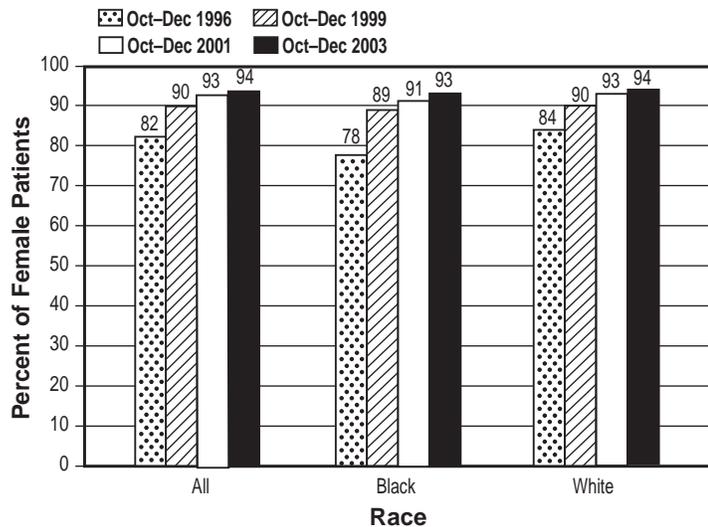
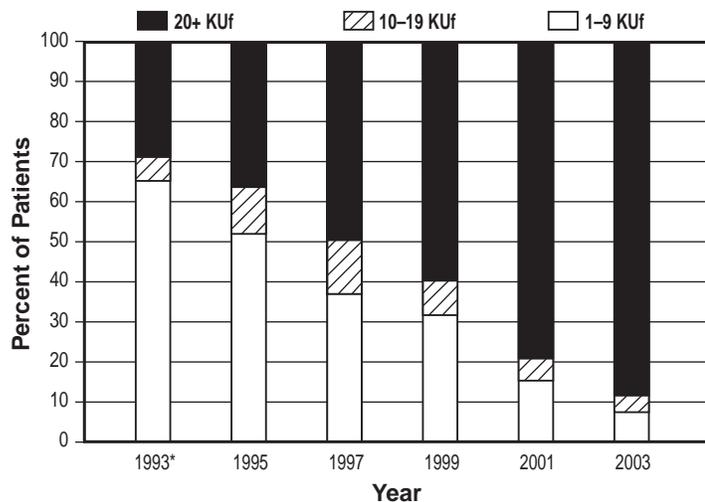


Figure 19 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category October–December 2003, compared to previous study years. The percent of patients dialyzed with a dialyzer with a KUF  $\geq 20$  mL/mmHg/hr increased from approximately 30% in late 1993 to approximately 89% in late 2003.

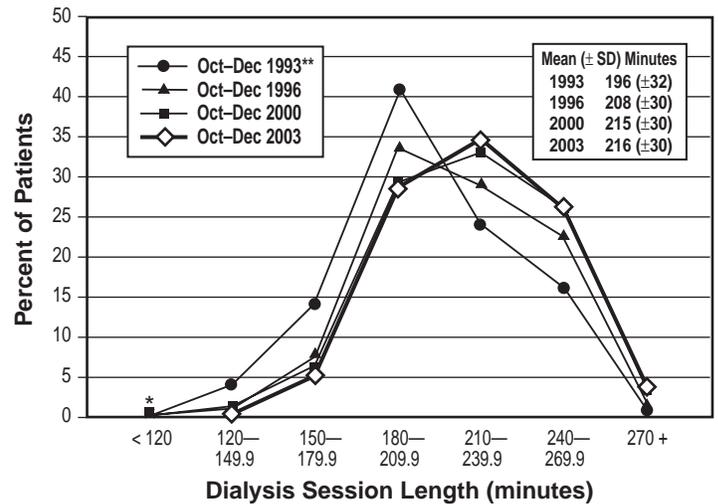
**Figure 19:** Percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.



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

Figure 20 shows a trend for slight increases in dialysis session lengths from late 1993 to late 2003.

**Figure 20:** Distribution of mean dialysis session length (minutes), October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.



\*\*Sixteen Network areas participated in the first ESRD Core Indicators Project assessment (October–December 1993); all Network areas participated in subsequent years.  
\*Value suppressed because  $n \leq 10$ .

## B. VASCULAR ACCESS

### 1. CPM Findings for October-December 2003

Data to assess three vascular access CPMs were collected in 2004. The time period from which these data were abstracted was October–December 2003. Results for these CPMs are included in this report.

**Vascular Access CPM I** — A primary arteriovenous 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:** 35% of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 2003 and August 31, 2003, [n = 1,360]) were dialyzed using an AVF on their last hemodialysis session during October–December 2003 (TABLE 8).

35% of all patients in the sample for analysis were dialyzed using an AVF during their last hemodialysis session October–December 2003 (TABLE 8).

**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:** 20% of all patients in the sample for analysis were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 2003 (FIGURE 21).

**Vascular Access CPM III** — A patient’s AV graft should be routinely monitored for stenosis. (See Vascular Access CPM III in Appendix 1 for a list of techniques and frequency of monitoring used to screen for the presence of stenosis).

**FINDING:** 77% of patients with an AV graft (n=3,099) had this graft routinely monitored for the presence of stenosis during October–December 2003.

**TABLE 8:** Vascular access type for incident<sup>a</sup> and all adult in-center hemodialysis patients during the last hemodialysis session of the study period, by selected patient characteristics, October-December 2003. 2004 ESRD CPM Project.

Patient Characteristic	Incident (n=1,360)			Prevalent (n=8,634)		
	AVF %	Graft %	Catheter %	AVF %	Graft %	Catheter %
TOTAL	35	26	40	35	38	27
GENDER						
Men	43	20	37	44	32	24
Women	24	33	43	25	45	30
RACE						
American Indian/ Alaska Native	71	*	*	52	30	18
Asian/Pacific Islander	52	*	*	47	37	16
Black	28	31	42	29	45	26
White	37	24	39	38	34	28
Other/Unknown	33	24	43	42	30	28
ETHNICITY						
Hispanic	44	28	28	38	39	23
Non-Hispanic	33	25	42	35	38	27
AGE GROUP (years)						
18-44	48	17	35	46	30	24
45-54	39	23	39	39	37	24
55-64	34	25	41	34	39	27
65-74	33	31	36	32	42	26
75+	27	27	45	30	38	32
CAUSE of ESRD						
Diabetes Mellitus	34	27	39	32	41	27
Hypertension	35	28	38	35	39	26
Glomerulonephritis	54	21	25	43	35	21
Other/Unknown	31	20	48	40	30	30
DURATION of DIALYSIS (years)						
< 0.5	31	18	51	21	17	62
0.5-0.9	36	28	36	36	28	35
1.0-1.9	N/A	N/A	N/A	39	37	23
2.0-2.9	N/A	N/A	N/A	40	42	19
3.0-3.9	N/A	N/A	N/A	36	45	19
4.0+	N/A	N/A	N/A	36	46	18

<sup>a</sup>An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2003 and August 31, 2003.

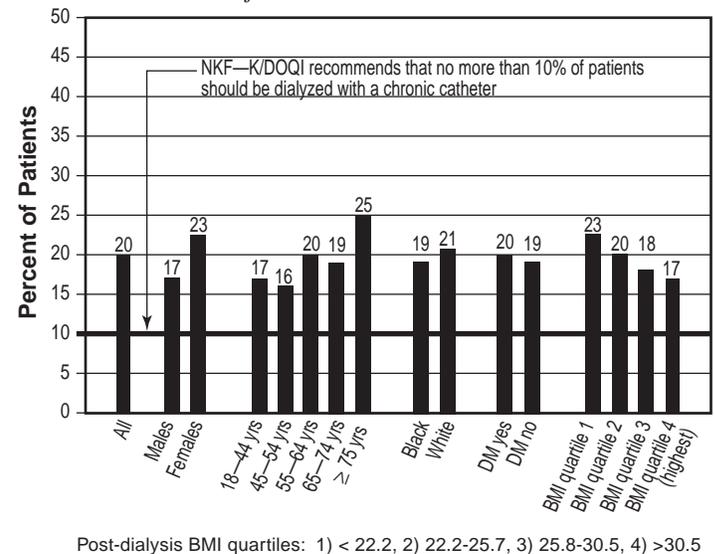
Note: Percentages may not add up to 100% due to rounding.

\*Value suppressed because n ≤ 10.

## 2. Other Vascular Access Findings for October-December 2003

Among prevalent patients, males, Whites, Hispanics, patients 18-44 years old, patients with causes of ESRD other than dia-

**Figure 21:** Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October-December 2003, by patient characteristics. 2004 ESRD CPM Project.



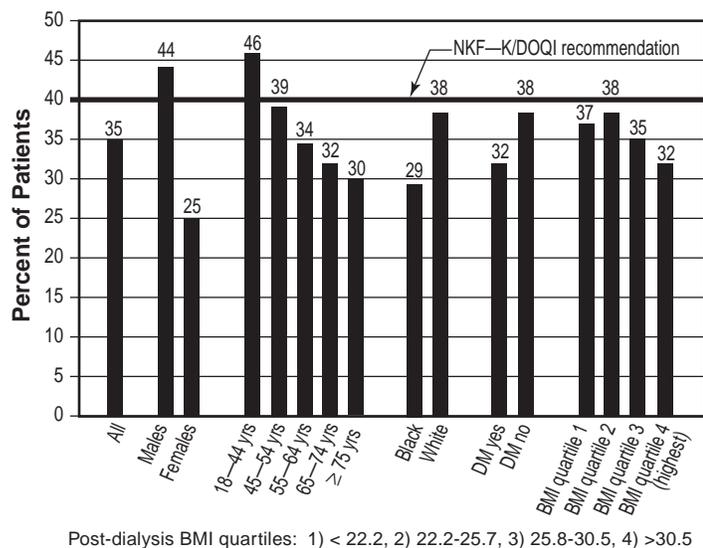
betes mellitus, and patients dialyzing six months or longer were more likely to be dialyzed with an AVF compared to women, Blacks, non-Hispanics, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLE 8). Most patient groups examined did not meet the current NKF-K/DOQI recommendation of 40% of prevalent patients having an AVF as their vascular access (4) (TABLE 8, FIGURE 22). The percent of prevalent patients with a catheter as their vascular access, by several patient characteristics, is shown in Table 8 and Figure 23. More women, Whites, patients ≥ 75 years old, and patients in the lowest quartile of post-dialysis BMI had a catheter access compared to men, Blacks, younger patients, and patients in higher quartiles of post-dialysis BMI.

More women were dialyzed with a chronic catheter compared to men (FIGURE 21). None of the patient groups examined met the current NKF-K/DOQI recommendation of less than 10% of chronic hemodialysis patients with a catheter as their vascular access (4).

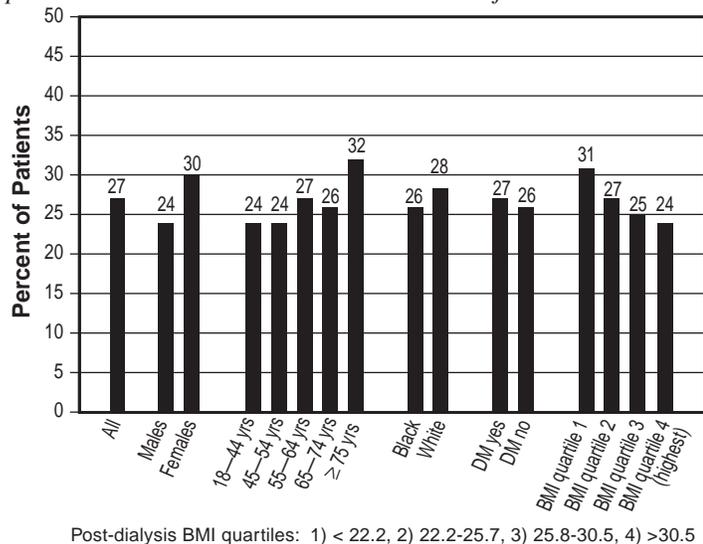
There was wide geographic variation in the percent of all patients dialyzed with an AVF; the percent ranged from 28% to 56% among the 18 Network areas (FIGURE 24, TABLE 9). This geographic variation in AVF use was also noted for incident patients, ranging from 22% to 61% among the 18 Network areas (FIGURE 25).

The percent of patients dialyzed with a catheter exhibited geographic variation, ranging from 19% to 37% among the 18 Network areas (FIGURE 26, TABLE 10). Chronic catheter use was 20% nationally, and ranged from 13% to 29% across the 18 Network areas (FIGURE 27).

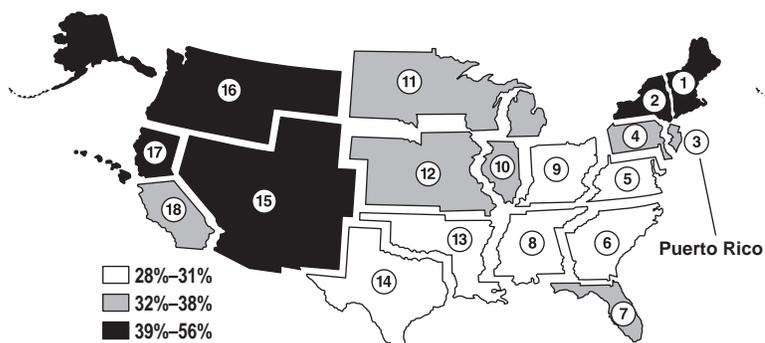
**Figure 22:** Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2003, by patient characteristics. 2004 ESRD CPM Project.



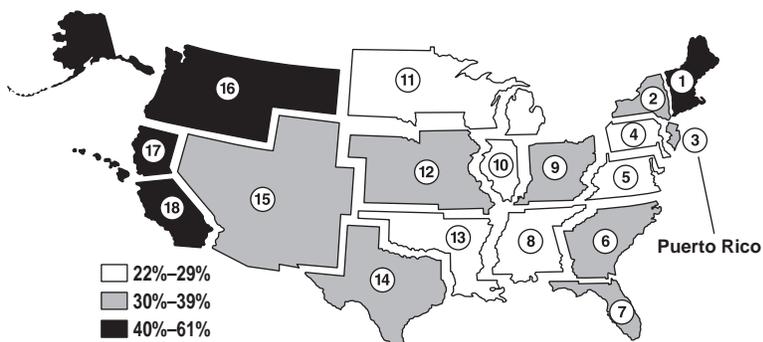
**Figure 23:** Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October-December 2003, by patient characteristics. 2004 ESRD CPM Project.



**Figure 24:** Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2003, by Network. 2004 ESRD CPM Project.

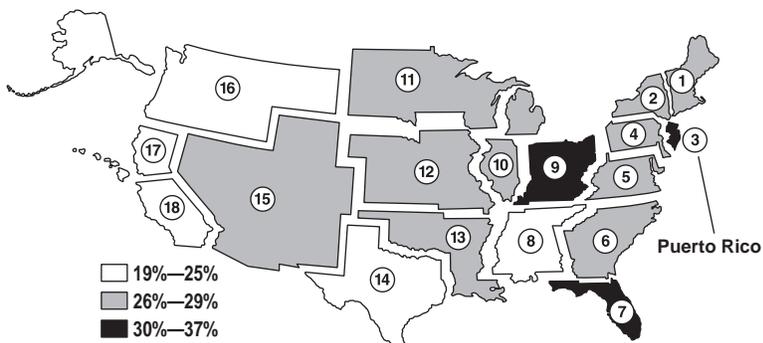


**Figure 25:** Percent of incident\* adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2003, by Network. 2004 ESRD CPM Project.

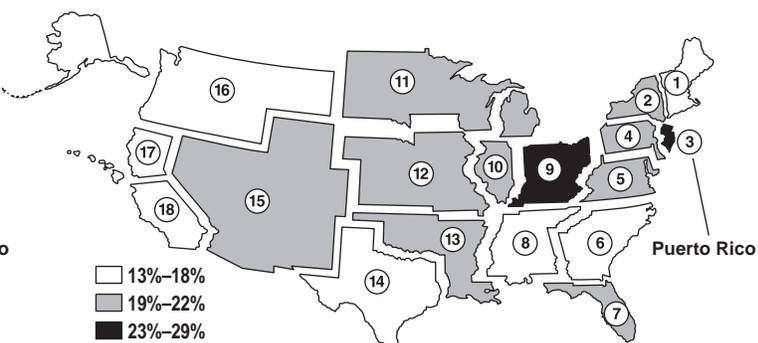


\*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2003 and August 31, 2003.

**Figure 26:** Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October-December 2003, by Network. 2004 ESRD CPM Project.



**Figure 27:** Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October-December 2003, by Network. 2004 ESRD CPM Project.



**TABLE 9:** Percent of all adult in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 2003, by gender, race, ethnicity, age, cause of ESRD, and Network. 2004 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	48	43	35	37	28	29	35	28	31	37	36	35	31	29	45	56	41	38	35	
GENDER																				
Men	57	54	40	45	35	39	43	35	40	47	44	46	44	36	55	65	50	47	44	
Women	37	32	26	27	20	20	26	20	20	25	26	24	18	21	35	44	29	29	25	
RACE																				
Black	45	40	26	34	25	26	30	27	24	35	28	29	28	26	26	33	33	39	29	
White	49	44	42	40	30	34	38	27	35	37	38	36	32	28	45	56	39	39	38	
ETHNICITY																				
Hispanic	50	60	36	*	*	*	29	*	*	47	*	*	*	25	50	39	43	39	38	
Non-Hispanic	48	41	33	38	27	29	37	28	30	35	36	35	30	32	43	57	40	38	35	
AGE GROUP (years)																				
18-44	62	54	40	46	42	40	39	32	28	46	55	42	47	54	48	68	44	54	46	
45-54	42	46	40	36	32	27	43	35	44	43	39	47	30	33	43	49	39	43	39	
55-64	60	45	32	37	24	25	33	28	38	32	28	39	34	26	46	50	40	33	34	
65-74	48	45	36	37	23	27	28	25	27	27	35	28	20	20	46	60	46	28	32	
75+	38	30	29	34	21	28	37	16	23	38	30	25	24	*	42	53	34	32	30	
CAUSE OF ESRD																				
Diabetes Mellitus	46	40	33	35	24	25	26	24	30	29	33	36	24	20	48	51	34	36	32	
Other Causes Combined	50	46	36	39	30	32	43	30	32	41	38	34	36	36	41	58	47	40	38	

\* Value suppressed because n ≤ 10.

**TABLE 10:** Percent of all adult in-center hemodialysis patients with a catheter access on their last hemodialysis session during October–December 2003, by gender, race, ethnicity, age, cause of ESRD, and Network. 2004 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	28	28	37	28	28	26	31	24	36	29	27	28	28	19	26	20	21	22	27
<b>GENDER</b>																			
Men	24	26	34	23	25	23	28	21	33	24	23	25	24	18	22	16	19	20	24
Women	32	29	41	34	31	29	35	28	40	34	32	31	31	20	29	25	25	24	30
<b>RACE</b>																			
Black	24	25	38	24	26	25	31	24	37	32	23	30	24	16	43	*	19	18	26
White	28	29	35	31	33	28	33	24	35	28	31	28	35	21	27	20	24	24	28
<b>ETHNICITY</b>																			
Hispanic	*	35	40	*	*	*	29	*	*	*	*	*	*	18	22	*	20	17	23
Non-Hispanic	28	27	36	28	28	26	31	24	36	30	27	28	28	20	27	20	22	26	27
<b>AGE GROUP (years)</b>																			
18-44	17	29	32	26	29	22	26	32	33	29	18	25	22	14	24	18	19	22	24
45-54	38	25	34	29	29	28	20	19	28	20	26	27	23	17	23	22	20	20	24
55-64	19	28	37	23	22	32	34	22	34	30	28	30	27	21	24	23	20	24	27
65-74	28	24	38	27	23	20	34	26	35	32	29	27	28	15	21	15	22	25	26
75+	33	32	42	35	36	28	36	24	47	33	30	30	38	29	38	21	25	21	32
<b>CAUSE OF ESRD</b>																			
Diabetes Mellitus	28	26	40	30	31	26	38	23	36	33	28	27	31	18	22	20	25	22	27
Other Causes Combined	27	28	35	27	26	26	26	25	36	27	26	29	25	20	30	20	19	22	26

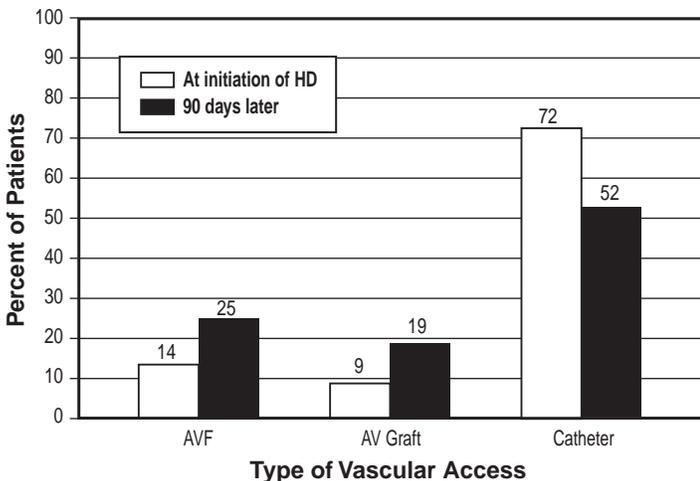
\* Value suppressed because n ≤ 10.

27% (n=2,301) of all patients in the sample for analysis were dialyzed with a catheter during their last hemodialysis session of the study period (TABLES 8, 10). The most common reasons for catheter placement were: no fistula or graft surgically planned (24%), the fistula or graft was maturing, not ready to cannulate (23%), and no fistula or graft surgically created at this time (22%) (TABLE 11). 13% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

75% of patients with an AVF or AV graft (n=6,238) had their vascular access monitored for stenosis during the study period. For this subset of patients, 76% were monitored with dynamic venous pressure, 9% with static venous pressure, 7% with the dilution technique, 2% with Color-flow Doppler, and 15% with "Other" techniques (groups not mutually exclusive).

14% of incident patients had an AVF as their vascular access upon initiation of a maintenance course of hemodialysis; 25% of incident patients had an AVF as their vascular access 90 days later (FIGURE 28). 72% of incident patients had a catheter as their vascular access upon initiation of a maintenance course of hemodialysis; 52% of incident patients had a catheter as their vascular access 90 days later (FIGURE 28).

**Figure 28:** Percent of incident\* adult in-center hemodialysis patients with different types of vascular access upon initiation of a maintenance course of hemodialysis and 90 days later. 2004 ESRD CPM Project.



\*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2003 and August 31, 2003.

**TABLE 11:** Reasons for catheter placement in adult in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2003. 2004 ESRD CPM Project.

Reason	n	(%)
<b>TOTAL</b>	<b>2,301</b>	<b>(100)</b>
No fistula or graft surgically planned	561	(24)
Patient preference	306	
Peripheral vascular disease	143	
Physician preference	85	
Patient size too small for AV fistula/graft	39	
Renal transplantation scheduled	22	
Fistula or graft maturing, not ready to cannulate	522	(23)
No fistula or graft surgically created at this time	517	(22)
All fistula or graft sites have been exhausted	301	(13)
Temporary interruption of fistula or graft use due to clotting, revision, or other reasons	271	(12)
Other	111	(5)

\*Note: Subtotals may not add up to 2,301 as respondents could choose multiple reasons. Percents may not add up to 100% due to rounding.

### 3. CPM and other Findings for October-December 2003 compared to previous study periods

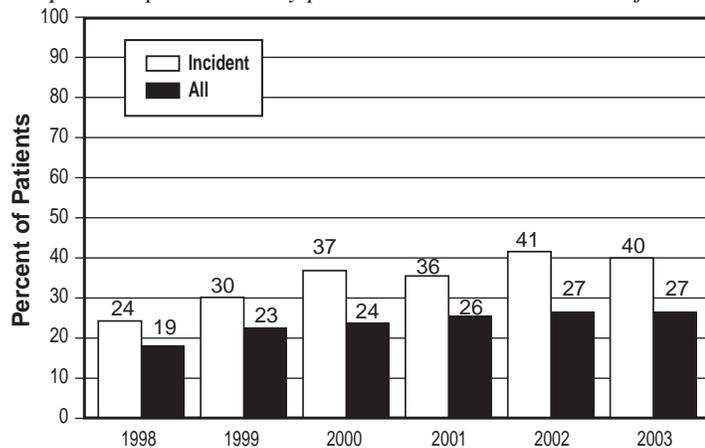
Although there was no change in the percent of patients dialyzed with a catheter on their last hemodialysis session during October-December 2003 compared to October-December 2002 (27% each period), more patients in 2002 and 2003 were dialyzed with a catheter compared to patients in years prior to 2002 (19%, 23%, 24%, and 26% in 1998, 1999, 2000, and 2001, respectively) (FIGURES 2, 29). A similar pattern was noted for incident patients, with 40% of patients dialyzed with a catheter on their last hemodialysis session in late 2003 compared to 41% of patients in late 2002 (FIGURE 29).

There has been some improvement in the percent of all patients dialyzed with an AVF on their last hemodialysis session from late 1998 to late 2003 (26% vs. 35%, respectively) (FIGURE 30). 26% of incident patients were dialyzed with an AVF on their last hemodialysis session in late 1998 compared to 35% in late 2003 (FIGURE 30).

14% of all patients were dialyzed with a chronic catheter continuously for 90 days or longer during late 1998 and 1999, compared to 20% of all patients during October-December 2003 (FIGURE 2).

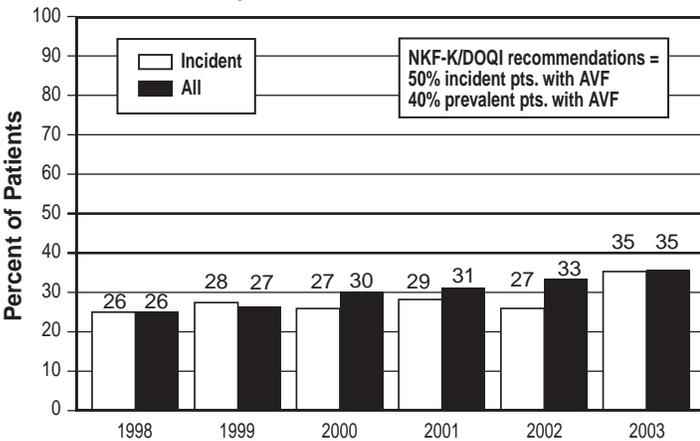
There was a 24% increase in the percent of reported dynamic venous pressure monitoring for patients with either an AVF or an AV graft as their vascular access from late 2001 to late 2003 (FIGURE 31).

**Figure 29:** Percent of adult in-center hemodialysis patients (all and incident\*) dialyzed with a catheter as their access on their last hemodialysis session during October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



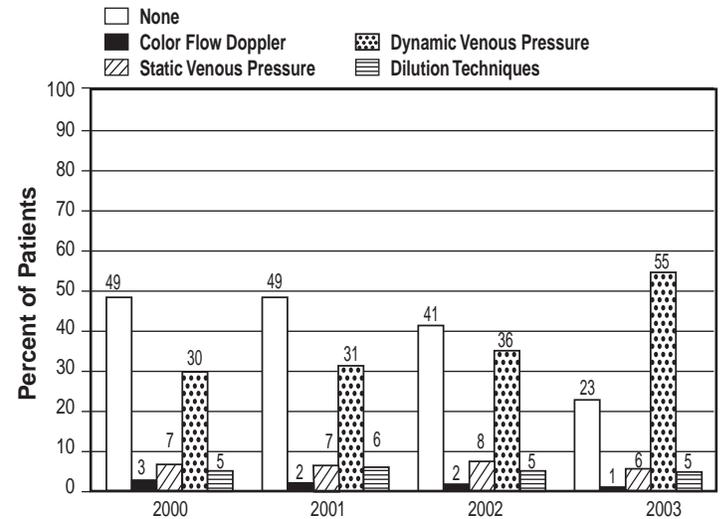
\*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, of the study year.

**Figure 30:** Percent of adult in-center hemodialysis patients (all and incident\*) dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



\*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, of the study year.

**Figure 31:** Types of stenosis monitoring reported for adult in-center hemodialysis patients with either an AV fistula or an AV graft as their vascular access on their last hemodialysis session during October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



See Appendix 1 for a complete description of the types of stenosis monitoring.

**C. ANEMIA MANAGEMENT**

**1. CPM Findings for October–December 2003**

Data were collected to assess three anemia management CPMs. The time period from which these data were abstracted was October–December 2003.

**Anemia Management CPM I** — The target hemoglobin is 11–12 g/dL (110–120 g/L). Patients with a mean hemoglobin > 12 g/dL (120 g/L) and not prescribed Epoetin were excluded from analysis for this CPM.

**FINDING:** For the last quarter of 2003, 36% of the in-center hemodialysis patients who met the inclusion criteria (n=8,441) had a mean hemoglobin 11–12 g/dL (110–120 g/L).

**Anemia Management CPM Ila** — For all anemic patients (hemoglobin < 11 g/dL [110 g/L]) 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 2003, 96% of the in-center hemodialysis patients who met the inclusion criteria (n=8,415) 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 Iib** — For all anemic patients (hemoglobin < 11 g/dL [110 g/L]) or patients prescribed Epoetin, at least one serum ferritin concentration ≥100 ng/mL and at least one transferrin saturation ≥ 20% were documented during the three-month study period.

**FINDING:** For the last quarter of 2003, 81% of the in-center hemodialysis patients who met the inclusion criteria (n=8,415) had at least one documented transferrin saturation ≥ 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 g/dL [110 g/L]), 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 ≥ 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:** 79% of the in-center hemodialysis patients who met the inclusion criteria (n=2,696) were prescribed intravenous iron in at least one month during October–December 2003.

**2. Other Anemia Management Findings for October–December 2003**

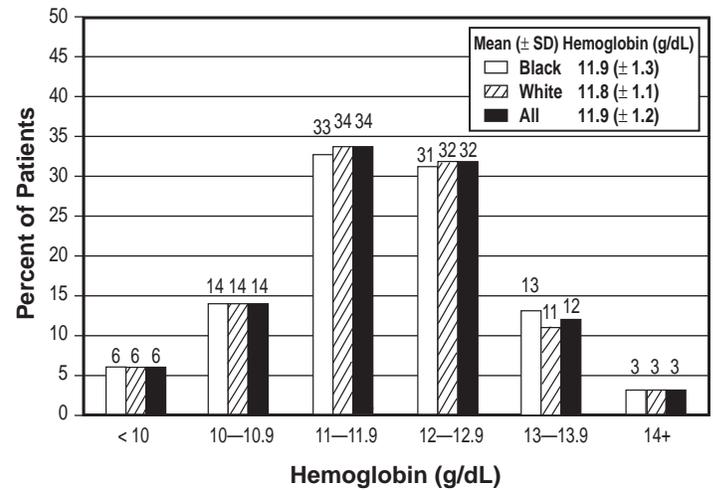
**NOTE:** The following findings apply to all the adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The distributions of mean hemoglobin values are shown in Figure 32 for all patients in the sample and for Black and White patients. The mean (± SD) hemoglobin value for all patients in this sample was 11.9 (± 1.2) g/dL (119 [±12] g/L). The mean hemoglobin values for gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters are shown in Table 12.

The mean hemoglobin value was lower for women and patients dialyzing less than six months compared to men and patients dialyzing six months or longer.

The mean hemoglobin value was higher for patients with a mean spKt/V ≥ 1.2 compared to patients with a mean spKt/V < 1.2, higher for patients with higher mean serum albumin values, and higher for patients dialyzed with an AVF or AV graft compared to patients dialyzed with a catheter (TABLE 12).

**Figure 32:** Distribution of mean hemoglobin values for adult in-center hemodialysis patients in the US, by race, October–December 2003. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**TABLE 12:** Mean hemoglobin values (g/dL) for adult in-center hemodialysis patients in the US, by patient characteristics, October–December 2003. 2004 ESRD CPM Project.

Patient Characteristic	Mean hemoglobin (g/dL)	Percent of patients with hemoglobin values					
		< 10	10-10.9	11-11.9	12-12.9	13-13.9	14+
<b>TOTAL</b>	<b>11.9</b>	<b>6</b>	<b>14</b>	<b>34</b>	<b>32</b>	<b>12</b>	<b>3</b>
<b>GENDER</b>							
Men	11.9	6	14	32	32	12	4
Women	11.8	6	14	35	32	11	2
<b>RACE</b>							
American Indian/ Alaska Native	12.1	*	10	26	37	17	4
Asian/Pacific Islander	11.9	4	10	42	32	9	3
Black	11.9	6	14	33	31	13	3
White	11.8	6	14	34	32	11	3
Other/Unknown	11.9	8	12	29	32	14	5
<b>ETHNICITY</b>							
Hispanic	11.9	7	12	34	31	12	4
Non-Hispanic	11.9	6	14	34	32	12	3
<b>AGE GROUP (years)</b>							
18-44	11.8	9	15	30	29	14	4
45-54	11.9	7	14	33	30	12	4
55-64	11.8	6	14	33	31	13	3
65-74	11.8	5	13	36	32	11	2
75+	11.9	5	13	35	35	11	3
<b>CAUSE of ESRD</b>							
Diabetes mellitus	11.8	6	14	34	32	11	3
Hypertension	11.9	6	13	34	31	13	3
Glomerulonephritis	11.9	6	14	34	32	11	3
Other/Unknown	11.8	8	14	31	32	11	3
<b>DURATION of DIALYSIS (years)</b>							
< 0.5	11.3	19	24	26	19	10	2
0.5-0.9	12.1	5	11	27	35	18	5
1.0-1.9	12.0	4	12	33	38	11	2
2.0-2.9	11.9	4	13	36	34	10	2
3.0-3.9	11.9	4	12	38	33	11	3
4.0+	11.9	5	12	37	30	11	4
<b>MEAN spKt/V</b>							
≥ 1.2	11.9	6	13	34	32	12	3
< 1.2	11.7	12	18	28	26	13	4
<b>MEAN SERUM ALBUMIN (g/dL)</b>							
≥ 3.5/3.2 BCG/BCP <sup>^</sup>	12.0	4	12	34	34	13	3
< 3.5/3.2 BCG/BCP	11.3	16	23	30	23	7	2
<b>ACCESS TYPE</b>							
AVF	12.0	5	12	34	34	13	4
AV Graft	11.9	4	13	36	33	11	3
Catheter	11.6	11	17	30	28	11	3

\* Value suppressed because n ≤ 10.

<sup>^</sup> BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

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

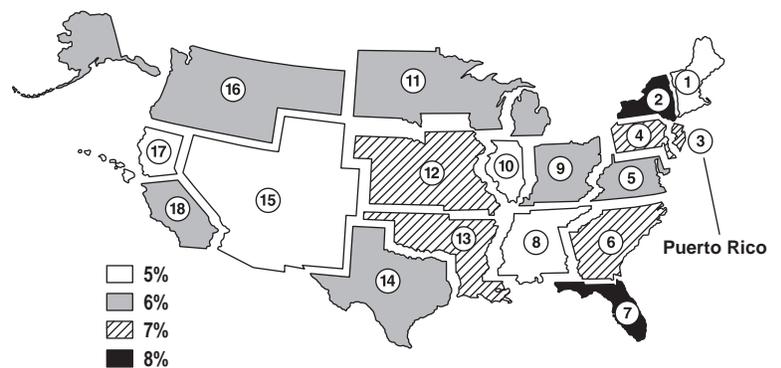
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

The prevalence of patients with mean hemoglobin < 10 g/dL (100g/L) was 6% nationally and ranged from 5% to 8% among Networks (FIGURE 33). The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was higher in patients dialyzing less than 6 months compared to those dialyzing 6 months or longer and higher in patients 18-44 years of age compared to older patients.

A higher proportion of patients with a mean spKt/V < 1.2 compared to patients with higher mean spKt/V values had a mean hemoglobin value <10 g/dL (100g/L). A higher proportion of patients dialyzed with a catheter had a mean hemoglobin < 10 g/dL (100 g/L) compared to patients dialyzed with either an AVF or an AV graft. A higher proportion of patients with a mean serum albumin < 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) compared to patients with higher mean serum albumin values had a mean hemoglobin < 10 g/dL (100 g/L) (TABLE 12).

**Figure 33:** Percent of adult in-center hemodialysis patients with mean hemoglobin < 10 g/dL, by Network, October–December 2003. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

The percent of all patients with mean hemoglobin ≥ 11 g/dL (110 g/L) was 80% nationally and ranged from 77% to 83% by Network (TABLE 13, FIGURES 34, 35).

The percent of patients with mean hemoglobin ≥ 11 g/dL (110 g/L) by selected patient characteristics and clinical parameters is shown in Figure 36. More patients dialyzing for six months or longer had a mean hemoglobin ≥ 11 g/dL (110 g/L) compared to patients dialyzing less than six months (83% vs. 57%, respectively). A higher percent of patients dialyzed with an AVF or an AV graft met this threshold compared to patients dialyzed with a catheter (84% and 83% compared to 72%, respectively). Patients with higher mean spKt/V and serum albumin values were more likely to meet this hemoglobin target than patients with lower spKt/Vs and serum albumin values.

**TABLE 13:** Percent of adult in-center hemodialysis patients with mean hemoglobin  $\geq 11$  g/dL, by gender, race, ethnicity, age, access type, mean serum albumin, and Network, October–December 2003. 2004 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	81	81	82	80	79	78	77	80	80	83	81	80	77	79	83	78	82	83	80	
GENDER																				
Men	83	79	80	80	82	79	77	79	81	85	82	79	76	78	82	81	79	81	80	
Women	79	82	85	79	76	77	77	81	78	82	80	81	78	80	84	75	85	84	80	
RACE																				
Black	82	81	83	82	79	77	72	79	81	85	82	73	76	80	81	67	86	84	79	
White	82	79	84	77	79	78	81	81	80	82	79	82	77	78	81	80	80	82	80	
ETHNICITY																				
Hispanic	78	87	78	85	*	*	81	*	*	81	86	93	*	76	80	85	83	82	81	
Non-Hispanic	81	80	84	79	79	78	77	80	80	83	81	79	77	81	85	78	82	83	80	
AGE GROUP (years)																				
18-44	78	78	85	76	77	75	75	76	68	82	76	71	72	79	82	72	79	76	76	
45-54	78	81	82	78	74	75	75	83	82	83	79	71	82	71	87	75	89	82	79	
55-64	81	83	77	81	79	74	71	75	78	88	77	83	77	81	88	80	81	86	80	
65-74	82	77	84	80	83	83	80	81	82	82	83	85	73	79	82	87	80	85	81	
75+	83	84	83	80	81	83	83	85	83	81	86	84	84	86	77	77	82	84	83	
ACCESS TYPE																				
AVF	86	83	87	83	84	79	89	77	85	86	84	82	83	80	88	83	86	85	84	
AVG	78	82	84	84	83	83	77	85	82	86	82	82	81	81	84	79	85	89	83	
Catheter	76	77	76	70	70	67	65	73	73	78	76	73	65	73	74	67	69	68	72	
MEAN SERUM ALBUMIN																				
$\geq 3.5/3.2$ g/dL	84	87	87	85	85	82	82	84	84	86	85	82	82	82	87	82	87	87	84	
BCG/BCP <sup>a</sup>																				
$< 3.5/3.2$ g/dL																				
BCG/BCP	68	58	66	62	56	55	61	61	66	70	64	70	55	62	64	62	60	59	62	

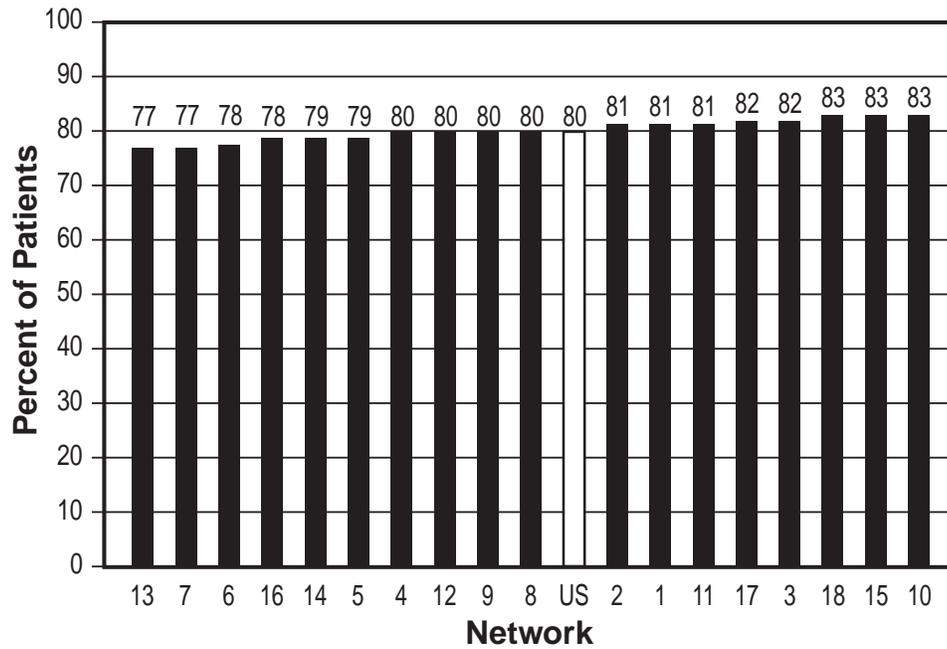
\*Value suppressed because  $n \leq 10$ .

<sup>a</sup> bromocresol green/bromocresol purple laboratory methods

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

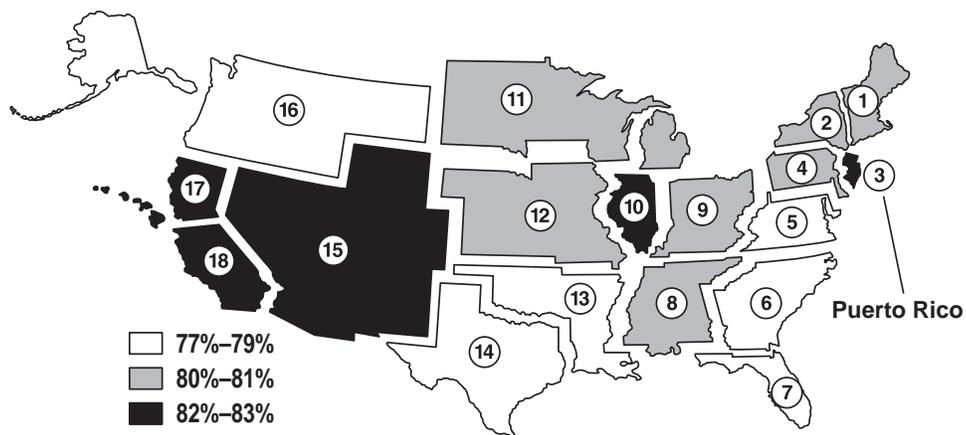
Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 34:** Percent of adult in-center hemodialysis patients with mean hemoglobin  $\geq 11$  g/dL, by Network, October–December 2003. 2004 ESRD CPM Project.



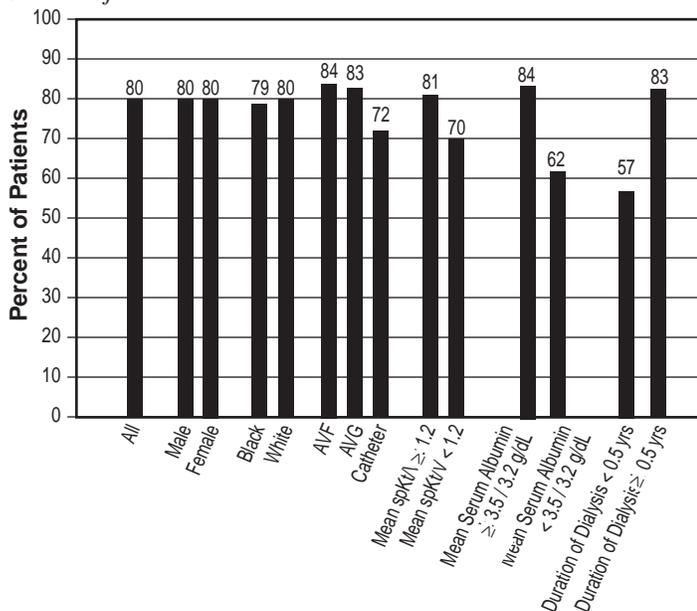
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 35:** Percent of adult in-center hemodialysis patients with mean hemoglobin  $\geq 11$  g/dL, by Network, October–December 2003. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 36:** Percent of adult in-center hemodialysis patients with mean hemoglobin  $\geq 11$  g/dL, by selected patient characteristics and clinical parameters, October-December 2003. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

During this study period, data were collected on additional measures related to anemia management (TABLE 14).

The national average ( $\pm$  SD) transferrin saturation for the patients in the sample was 29.3 ( $\pm$  12.1)% and ranged from 27.1% to 32.0% among the 18 Network areas (TABLE 14). Table 14 also provides the percent of patients with mean transferrin saturation  $\geq 20\%$  nationally (81%) and by Network area, ranging from 72% to 87%.

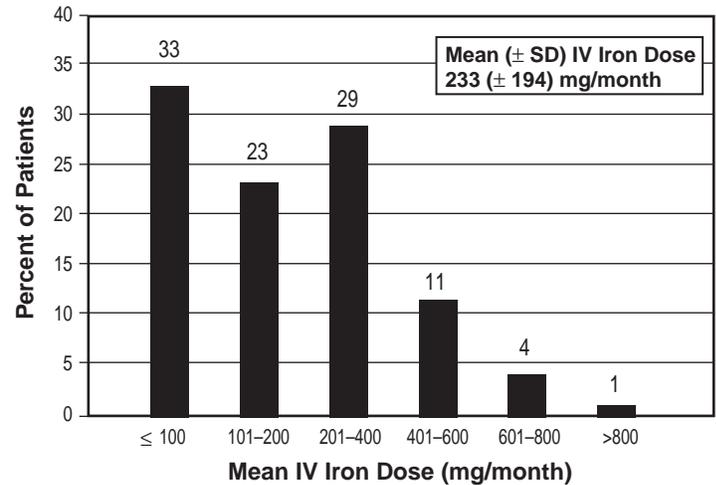
The national average ( $\pm$  SD) serum ferritin concentration for the patients in the sample was 596 ( $\pm$  419)ng/mL and ranged from 517 to 660 ng/mL among the 18 Network areas. The percent of patients with a mean serum ferritin concentration  $\geq 100$  ng/mL nationally was 94%, ranging from 91% to 97% among the 18 Network areas (TABLE 14).

66% of all patients in the sample 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 65%, ranging from 55% to 73% among the 18 Network areas (TABLE 14).

For the subset of patients with both mean transferrin saturation  $< 20\%$  and mean serum ferritin concentration  $< 100$  ng/mL (n=209 or 2% of patients), only 74% were prescribed IV iron at least once during the three-month study period.

The mean administered IV iron dose was 233 ( $\pm$  194) mg/month. The distribution of mean administered IV iron doses (mg/month) is shown in Figure 37.

**Figure 37:** Distribution of mean intravenous iron doses (mg/month) for adult in-center hemodialysis patients, October-December 2003. 2004 ESRD CPM Project.



NOTE: For this report, missing monthly IV iron doses were considered to be zero. For the 2002 ESRD CPM Annual Report (FIGURE 40, pg. 36), missing monthly IV iron doses were considered missing.

96% of all patients were prescribed Epoetin, of which 94% were prescribed Epoetin by the IV route; and 7% by the SC route (groups not mutually exclusive). Prescribed SC administration, the route recommended by the NKF-K/DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure (5, 16), ranged from 3% to 16% among the 18 Network areas (TABLE 14). The mean ( $\pm$  SD) weekly Epoetin dose was 271.3 ( $\pm$  251.8) units/kg/week by the IV route, and 206.2 ( $\pm$  184.8) units/kg/week by the SC route.

17 (0.2%) patients in the sample for analysis were prescribed Darbepoetin at least once during the three-month study period.

**TABLE 14:** Regional variation for various anemia management measures for adult in-center hemodialysis patients including the percent of patients with mean hemoglobin  $\geq 11$  g/dL, mean hemoglobin (g/dL), and mean serum albumin  $\geq 4.0$  BCG<sup>^</sup> for these patients nationally and by Network, October-December 2003. 2004 ESRD CPM Project.

ANEMIA MANAGEMENT MEASURE:	NETWORK																		US
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
Percent of patients with mean hemoglobin $\geq 11$ g/dL	81	81	82	80	79	78	77	80	80	83	81	80	77	79	83	78	82	83	80
Mean hemoglobin (g/dL)	11.8	11.8	11.9	11.7	11.8	11.8	11.7	11.8	12.0	12.0	12.0	11.7	11.8	11.8	12.0	11.8	11.9	11.8	11.9
Percent of patients with mean serum albumin $\geq 4.0$ g/dL BCG <sup>^</sup>	30	40	35	35	34	40	36	43	41	46	38	33	39	43	34	32	42	41	39
Average transferrin saturation (TSAT) (%)	29.0	31.4	28.8	28.6	29.0	29.4	28.6	27.8	28.0	30.2	29.8	27.2	28.7	29.6	29.1	27.1	29.0	32.0	29.3
Percent of patients with mean TSAT $\geq 20\%$	79	79	80	81	83	85	80	78	74	82	81	75	81	83	82	72	78	87	81
Average serum ferritin concentration (ng/mL)	542	641	538	587	548	596	656	613	601	649	552	604	624	620	525	517	537	660	596
Percent of patients with mean serum ferritin concentration $\geq 100$ ng/mL	92	92	91	94	91	94	96	95	94	95	94	95	96	95	93	97	94	94	94
Percent of patients with mean serum ferritin concentration $> 800$ ng/mL	22	31	19	24	21	24	31	26	24	28	22	27	28	28	18	17	19	31	25
Percent of all patients with IV iron prescribed	65	64	73	65	69	66	66	67	70	65	66	64	66	67	65	64	55	56	65
Mean IV iron dose (mg/month)	224	245	245	244	249	226	248	243	229	223	263	226	242	217	240	224	186	219	233
Percent of patients prescribed Epoetin	98	97	99	96	97	96	98	96	97	95	97	97	96	96	96	96	96	96	96
Percent of patients * with subcutaneous Epoetin prescribed	4	4	10	*	3	*	3	*	11	4	4	6	7	12	6	11	13	16	7
Percent of patients with mean hemoglobin $< 11$ g/dL with Epoetin prescribed	99	96	99	99	96	94	98	96	94	95	96	96	97	96	96	96	98	92	96

<sup>^</sup>For subset of patients with serum albumin tested by the bromocresol green (BCG) laboratory method

\*Among patients prescribed Epoetin

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

### 3. CPM and other Findings for October-December 2003 compared to previous study periods

NOTE: The following findings apply to all the adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

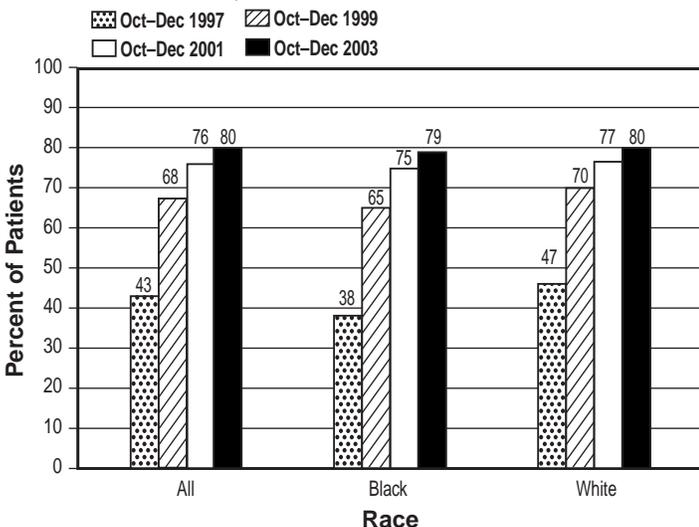
The mean hemoglobin ( $\pm$  SD) from October–December 2001 to October–December 2003 increased from 11.7 ( $\pm$  1.2) g/dL (117 [ $\pm$  12] g/L) to 11.9 ( $\pm$  1.2) g/dL (119 [ $\pm$  12] g/L) (FIGURE 7), and the percent of patients with a mean hemoglobin  $\geq$  11 g/dL (110 g/L) increased significantly from 76% to 80% (FIGURES 6, 38).

In addition to the improvement in the percent of patients with mean hemoglobin  $\geq$  11 g/dL (110 g/L), there was also a decrease in the percent of patients with mean hemoglobin < 10 g/dL (100 g/L). In October–December 2001, 9% of Black patients and 7% of White patients had a mean hemoglobin < 10 g/dL (100 g/L), while in October–December 2003, 6% of Black patients and 6% of White patients had a mean hemoglobin < 10 g/dL (100 g/L).

Figure 39 depicts the trend for increasing weekly Epoetin dosing (units/kg/week) for selected years from late 1997 to late 2003. SC Epoetin doses were systematically lower than IV Epoetin doses at all hemoglobin categories examined. Of the patients prescribed Epoetin, 7% of patients were prescribed SC Epoetin in late 2003.

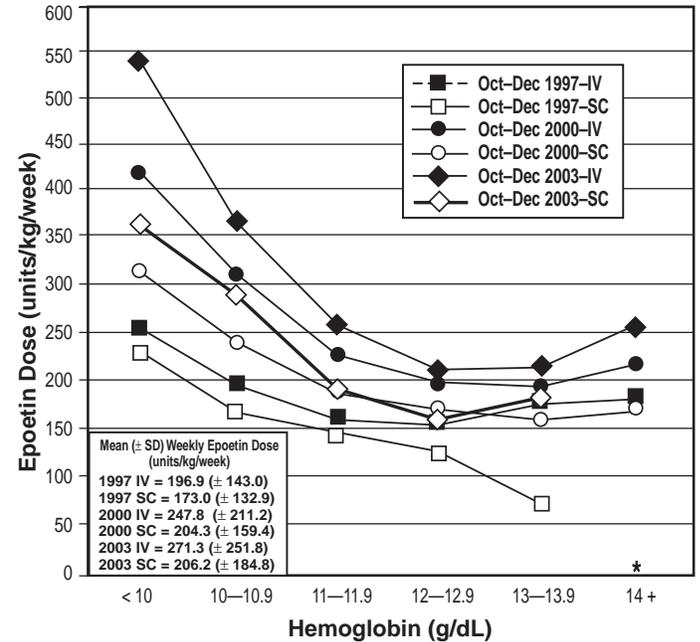
Figure 40 depicts the status of iron stores for the sampled patients in late 2003 compared to selected previous study periods. 65% of patients were prescribed IV iron in late 2003 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 74% of patients were prescribed IV iron at least once over the three-month study period in late 2003, compared to 37% in late 1996.

**Figure 38:** Percent of adult in-center hemodialysis patients with mean hemoglobin values  $\geq$  11 g/dL, by race, October–December 2003 compared to previous study periods. 2004 ESRD CPM Project.



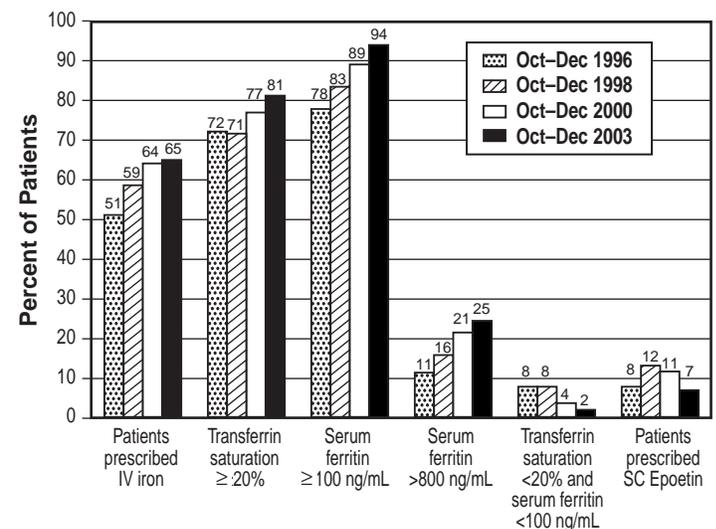
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 39:** Mean prescribed weekly Epoetin dose (units/kg/week) for adult in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 2003 compared to selected previous study periods. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.  
\*Value suppressed because n  $\leq$  10.

**Figure 40:** Percent of adult in-center hemodialysis patients with specific anemia management indicators, October–December 2003 compared to selected previous study periods. 2004 ESRD CPM Project.



**D. SERUM ALBUMIN**

**1. CPM Findings for October–December 2003**

Because serum albumin is not considered to be an official CPM for this project, there are no CPM findings to report for this section.

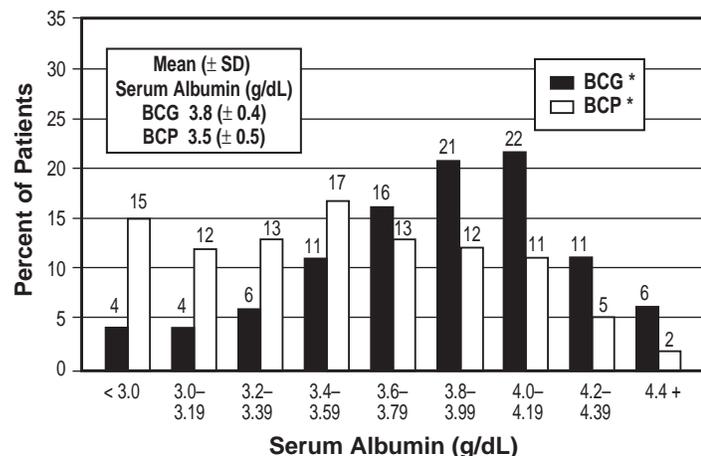
**2. Other Serum Albumin Findings for October–December 2003**

The two commonly used laboratory methods for determining serum albumin values, bromcresol green (BCG) and bromcresol purple (BCP), have been reported to yield systematically different results (6). Therefore, we assessed the serum albumin values reported for these two methods separately. The mean ( $\pm$  SD) serum albumin value for patients whose value was determined by the BCG method (n=8,104) was 3.8 ( $\pm$  0.4) g/dL (38 [ $\pm$  4] g/L), and by the BCP method (n=530) was 3.5 ( $\pm$  0.5) g/dL (35 [ $\pm$  5] g/dL) (FIGURE 41).

Mean serum albumin values < 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) are defined as inadequate for the purpose of this report and have been shown to be markers for diminished survival (29-31). Figure 41 displays the distribution of serum albumin values by laboratory method.

The percents of patients with mean serum albumin  $\geq$  4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) and  $\geq$  3.5/3.2 g/dL (35/32 g/L)(BCG/BCP) by gender, race, ethnicity, age, diagnosis groups, duration of dialysis, and selected clinical parameters are shown in Table 15. A higher percent of men, Blacks, Hispanics, patients 18-44 years old, patients with causes of ESRD other than diabetes mellitus, and patients dialyzing six months or longer had a mean serum albumin  $\geq$  4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) compared to women, Whites, non-Hispanics, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLES

**Figure 41:** Distribution of mean serum albumin for adult in-center hemodialysis patients, by laboratory method, October–December 2003. 2004 ESRD CPM Project.



\* Note: BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

15, 16, FIGURES 42, 43). Only 21% of patients dialyzing less than six months achieved a serum albumin that met the outcome goal of  $\geq$  4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) compared to 41% of patients dialyzing six months or more.

**TABLE 15:** Percent of adult in-center hemodialysis patients with mean serum albumin values  $\geq$  4.0/3.7 g/dL (BCG/BCP)\* and  $\geq$  3.5/3.2 g/dL (BCG/BCP) in the US, by patient characteristics, October-December 2003. 2004 ESRD CPM Project.

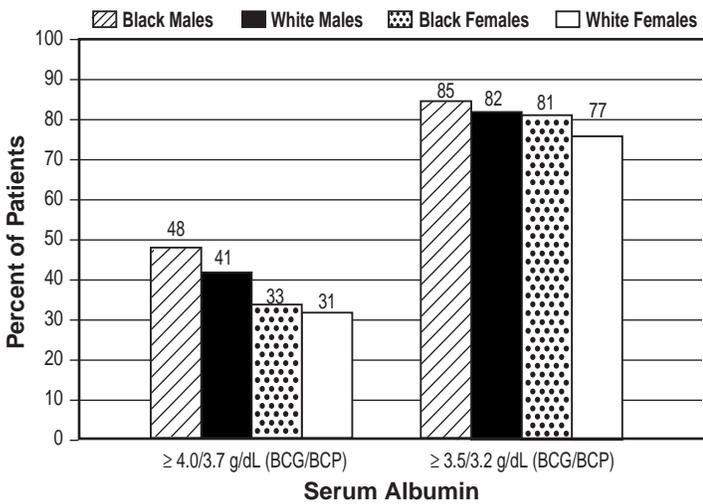
Patient Characteristic	Percent of Patients with Mean Serum Albumin $\geq$ 4.0/3.7 g/dL	Percent of Patients with Mean Serum Albumin $\geq$ 3.5/3.2 g/dL
<b>TOTAL</b>	<b>39</b>	<b>81</b>
<b>GENDER</b>		
Men	44	84
Women	32	79
<b>RACE</b>		
American Indian/Alaska Native	25	74
Asian/Pacific Islander	48	87
Black	41	83
White	36	80
Other/Unknown	43	84
<b>ETHNICITY</b>		
Hispanic	42	83
Non-Hispanic	38	81
<b>AGE GROUP (years)</b>		
18-44	53	87
45-54	45	83
55-64	40	81
65-74	34	82
75+	27	76
<b>CAUSE of ESRD</b>		
Diabetes mellitus	31	78
Hypertension	45	85
Glomerulonephritis	49	86
Other/Unknown	42	81
<b>DURATION of DIALYSIS (years)</b>		
< 0.5	21	58
0.5-0.9	35	78
1.0-1.9	39	85
2.0-2.9	39	86
3.0-3.9	45	84
4.0+	44	87
<b>MEAN spKt/V</b>		
$\geq$ 1.2	39	82
< 1.2	32	73
<b>MEAN Hgb (g/dL)</b>		
$\geq$ 11	42	86
< 11	25	64
<b>ACCESS TYPE</b>		
AVF	47	87
AF Graft	40	85
Catheter	25	67

\* Note: BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.  
 Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Patients with higher mean hemoglobin and mean spKt/V values had a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) compared to patients with lower mean hemoglobin and mean spKt/V values. More patients dialyzed with either an AVF or an AV graft compared to patients dialyzed with a catheter had a mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) (47% and 40% vs. 25% respectively) (TABLE 15).

Nationally, 39% of patients had mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) ranging from 31% to 45% among the 18 Networks; 81% of patients had mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) ranging from 77% to 85% among the 18 Networks. The percent of patients in each Network area, by gender, race, ethnicity, age group and cause of ESRD, with mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) is shown in Table 16.

**Figure 42:** Percent of adult in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)\* and  $\geq 3.5/3.2$  g/dL (BCG/BCP), by race and gender, October–December 2003. 2004 ESRD CPM Project.



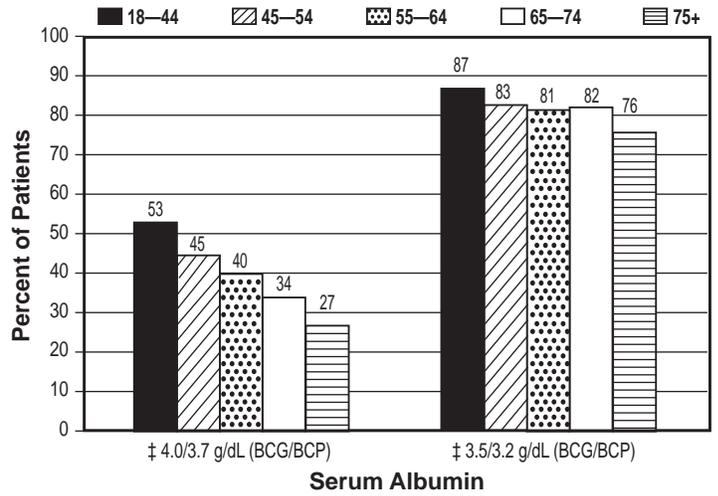
\* Note: BCG/BCP = bromocresol green/bromocresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**2. Findings for October–December 2003 compared to previous study periods**

No clinically important changes or improvements were noted in the proportion of adult in-center hemodialysis patients with a serum albumin that met the outcome goal of  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) during October–December 2003 compared to previous study periods.

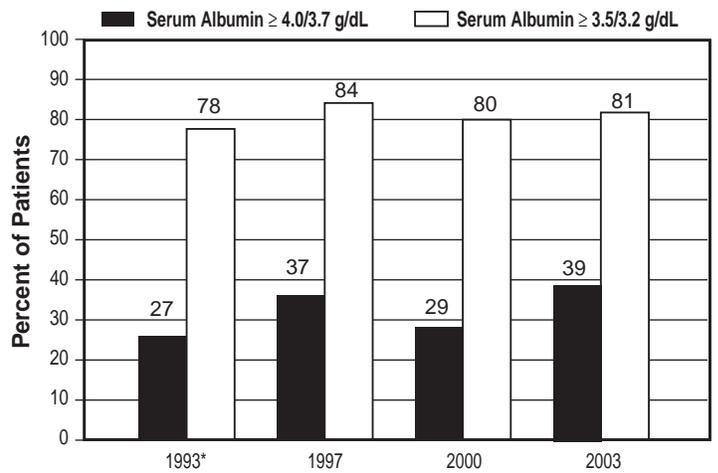
Figure 44 shows the percent of patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) and the percent of patients with mean serum albumin values  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) during October–December 2003 compared to selected previous study periods.

**Figure 43:** Percent of adult in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)\* and  $\geq 3.5/3.2$  g/dL (BCG/BCP), by age, October–December 2003. 2004 ESRD CPM Project.



\* Note: BCG/BCP = bromocresol green/bromocresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 44:** Percent of adult in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)\*\* and  $\geq 3.5/3.2$  g/dL (BCG/BCP), October–December 2003 compared to selected previous study periods. 2004 ESRD CPM Project.



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

\*\* Note: BCG/BCP = bromocresol green/bromocresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**TABLE 16:** Percent of adult in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP method)\*\* by gender; race, ethnicity, age, cause of ESRD, and Network, October-December 2003. 2004 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	32	40	33	35	33	40	37	43	40	45	37	34	40	43	34	31	42	41	39	
GENDER																				
Men	34	49	34	37	43	50	39	49	43	53	40	39	47	54	40	40	46	42	44	
Women	30	29	31	32	23	32	35	36	37	35	34	28	33	32	27	20	37	39	32	
RACE																				
Black	33	42	28	42	35	41	41	47	38	51	39	40	45	44	33	*	34	42	41	
White	31	36	37	31	27	40	34	34	42	40	36	30	34	42	35	31	37	40	36	
ETHNICITY																				
Hispanic	38	48	39	*	*	*	36	*	*	42	*	*	*	45	36	33	50	41	42	
Non-Hispanic	32	38	30	34	33	40	38	42	40	43	36	34	39	42	33	30	40	40	38	
AGE GROUP (years)																				
18-44	46	62	39	52	58	50	58	57	52	62	55	51	52	51	35	46	56	58	53	
45-54	36	45	46	42	29	48	39	50	40	53	43	39	42	50	57	39	54	42	45	
55-64	32	36	32	42	36	37	40	42	45	52	41	29	40	48	28	31	46	38	40	
65-74	29	35	29	27	31	37	32	41	38	27	41	25	40	36	32	29	30	37	34	
75+	27	28	25	26	20	27	29	24	32	34	19	31	24	27	24	18	33	30	27	
CAUSE OF ESRD																				
Diabetes Mellitus	24	32	26	31	23	27	29	35	34	40	30	25	32	35	34	22	36	29	31	
Other Causes Combined	38	44	38	37	40	50	44	48	45	47	43	39	45	50	34	36	48	49	44	

\* Value suppressed because  $n \leq 10$ .

\*\* Note: BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

## VI. ADULT PERITONEAL DIALYSIS PATIENTS

This section describes the findings for adult peritoneal dialysis patients for selected CPMs and other quality indicators related to adequacy of peritoneal dialysis, anemia management, and serum albumin. Each of these sections is further broken down into three parts:

- (1) national findings for selected CPM results for October 2003–March 2004 (the serum albumin information is not considered a CPM for this report);
- (2) a description of other quality indicators or data analysis; and
- (3) a comparison of CPM and/or other indicators or findings for October 2003–March 2004 and previous study periods.

A national random sample of adult ( $\geq 18$  years) peritoneal dialysis patients who were alive on December 31, 2003, was selected (sample size=1,453). 1,377 patients (95%) were included in the sample for analysis.

### A. ADEQUACY OF PERITONEAL DIALYSIS

#### 1. CPM Findings for October 2003–March 2004

Data to assess three peritoneal dialysis adequacy CPMs were collected in 2004. The time period from which these data were abstracted was October 2003–March 2004. Tidal peritoneal dialysis patients ( $n=39$ ) were excluded from the peritoneal dialysis adequacy CPM calculations.

**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:** 86% of 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 (FIGURE 3).

**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 1).

**FINDING:** 44% of 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 ( $Kt/V_{urea}$  and creatinine clearance) calculated in a standard way as described in Peritoneal Dialysis Adequacy CPM II in Appendix 1 (FIGURE 3).

**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 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For CCPD patients (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 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For NIPD patients (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 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

**FINDING:** 70% of CAPD patients had a mean weekly  $Kt/V_{urea} \geq 2.0$  and a mean weekly creatinine clearance  $\geq 60$  L/week/1.73 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (FIGURE 4).

**ALTERNATE FINDING:** 77% (156/203) of CAPD patients with a Peritoneal Equilibration Test (PET) result within 12 months of or during the study period met the revised 2000 NKF-K/DOQI thresholds for peritoneal dialysis adequacy (32) (a mean weekly  $Kt/V_{urea} \geq 2.0$  and for high and high-average transporters, a weekly creatinine clearance  $\geq 60$  L/week/1.73m<sup>2</sup>, for low and low-average transporters, a weekly creatinine clearance  $\geq 50$  L/week/1.73m<sup>2</sup>, OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period).

**FINDING:** 65% of cycler patients with a daytime dwell (CCPD patients) had a mean weekly  $Kt/V_{urea} \geq 2.1$  and a mean weekly creatinine clearance  $\geq 63$  L/week/1.73 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (FIGURE 4).

**FINDING:** 62% of cycler patients without a daytime dwell (NIPD patients) had a mean weekly  $Kt/V_{urea} \geq 2.2$  and a mean weekly creatinine clearance  $\geq 66$  L/week/1.73 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (FIGURE 4).

**2. Other Peritoneal Dialysis Adequacy Findings for October 2003-March 2004**

There were 466 patients categorized as CAPD patients and 773 patients categorized as cycler patients during the study period. Tidal peritoneal dialysis patients (n=39) were excluded from the peritoneal dialysis 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 1,151 (86%) of the 1,338 patients included for these analyses during the 2004 study period.

Table 17 depicts the percent of CAPD patients by transporter type with a mean calculated weekly  $Kt/V_{urea}$  and a mean calculated weekly creatinine clearance meeting recommended NKF-K/DOQI guidelines for those patients with sufficient data to calculate adequacy measures.

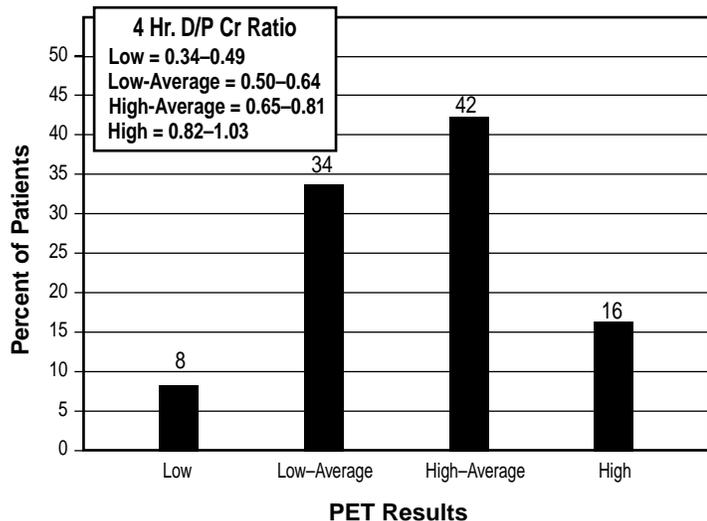
59% of cycler patients with a daytime dwell had a mean calculated weekly  $Kt/V_{urea}$  and 48% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2004 study period (TABLE 18). 56% of cycler patients without a daytime dwell had a mean calculated weekly  $Kt/V_{urea}$  and 44% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2004 study period.

40% of patients (n=533) had one or more PET results within 12 months of or during the study period. The distribution of PET results is depicted in Figure 45.

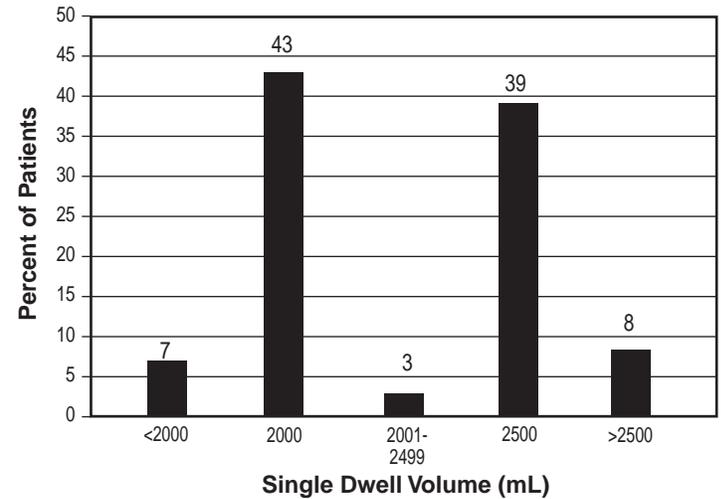
43% of CAPD patients had a single prescription volume of 2,000 mL and 39% had a single prescription volume of 2,500 mL (FIGURE 46).

33% of CAPD patients had a total prescription volume of 8,000 mL and another 33% had a total prescription volume of 10,000 mL (FIGURE 47).

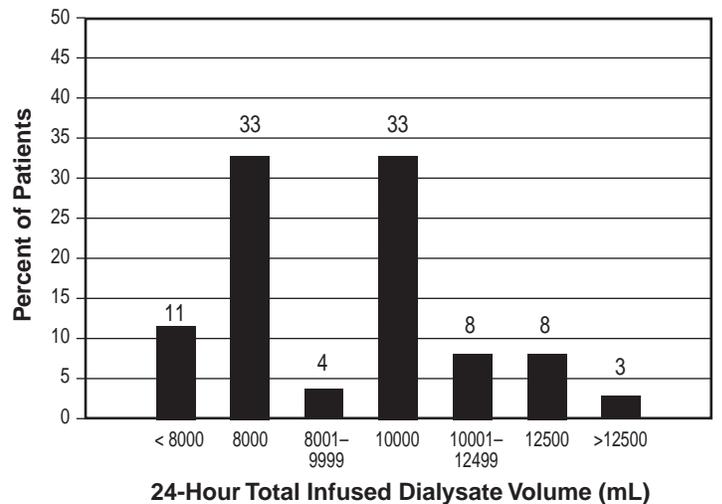
**Figure 45:** Distribution of Peritoneal Equilibration Test (PET) results for adult peritoneal dialysis patients, October 2003-March 2004. 2004 ESRD CPM Project.



**Figure 46:** Distribution of single dwell volumes for adult CAPD patients, October 2003-March 2004. 2004 ESRD CPM Project.



**Figure 47:** Distribution of 24-hour total infused dialysate volumes for adult CAPD patients, October 2003-March 2004. 2004 ESRD CPM Project.



30% of all cycler patients had a single nighttime dwell volume of 2500 mL; 27% had a single nighttime dwell volume of 2,000 mL (FIGURE 48). 43% of all cycler patients had a mean of four nighttime exchanges, 28% had a mean of 5 nighttime exchanges, and another 13% had a mean of 3 nighttime exchanges (FIGURE 49).

10% (n = 77) of cycler patients did not have a daytime dwell. 39% of cycler patients with a daytime dwell had a mean single daytime dwell volume of 2,000 mL; 23% had a mean single daytime dwell volume of 2,500 mL (FIGURE 50). 54% of these patients had one daytime exchange, another 35% had two daytime exchanges (FIGURE 51).

**TABLE 17:** Percent of adult CAPD patients with mean ( $\pm$  SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, by transporter type (4 hr. D/P Cr Ratio), October 2003–March 2004, 2004 ESRD CPM Project.

Adequacy Measure	Oct 2000–Mar 2001		Oct 2001–Mar 2002		Oct 2002–Mar 2003		Oct 2003–Mar 2004	
	High-Avg/High*	Low/Low-Avg	High-Avg/High	Low/Low-Avg	High-Avg/High	Low/Low-Avg	High-Avg/High	Low/Low-Avg
<b>Weekly Kt/V<sub>urea</sub></b>								
% meeting NKF-K/DOQI <sup>^</sup>	75%	71%	73%	69%	74%	81%	59%	75%
mean ( $\pm$ SD)	2.35 ( $\pm$ 0.57)	2.35 ( $\pm$ 0.58)	2.41 ( $\pm$ 0.71)	2.40 ( $\pm$ 0.69)	2.36 ( $\pm$ 0.59)	2.37 ( $\pm$ 0.48)	2.24 ( $\pm$ 0.67)	2.34 ( $\pm$ 0.64)
median	2.26	2.32	2.27	2.23	2.26	2.40	2.09	2.29
<b>Weekly Creatinine Clearance (L/week/1.73 m<sup>2</sup>)</b>								
% meeting NKF-K/DOQI	76%	79%	73%	80%	66%	79%	70%	64%
mean ( $\pm$ SD)	83.6 ( $\pm$ 29.7)	73.0 ( $\pm$ 27.5)	79.9 ( $\pm$ 28.4)	77.5 ( $\pm$ 32.3)	80.1 ( $\pm$ 30.0)	72.9 ( $\pm$ 26.6)	78.1 ( $\pm$ 27.8)	75.9 ( $\pm$ 28.4)
median	78.6	68.5	72.5	67.6	72.8	69.6	74.3	71.3

<sup>^</sup> For CAPD patients, the delivered PD dose should be a weekly KtV<sub>urea</sub>  $\geq$  2.0 and a weekly creatinine clearance  $\geq$  60 L/week/1.73m<sup>2</sup> for high-average and high transporters, and  $\geq$  50 L/week/1.73m<sup>2</sup> for low and low-average transporters.

\* Transporter type (4 hr. D/P Cr Ratio): Low = 0.34-0.49; Low-Average = 0.50-0.64; High-Average = 0.65-0.81; High = 0.82-1.03

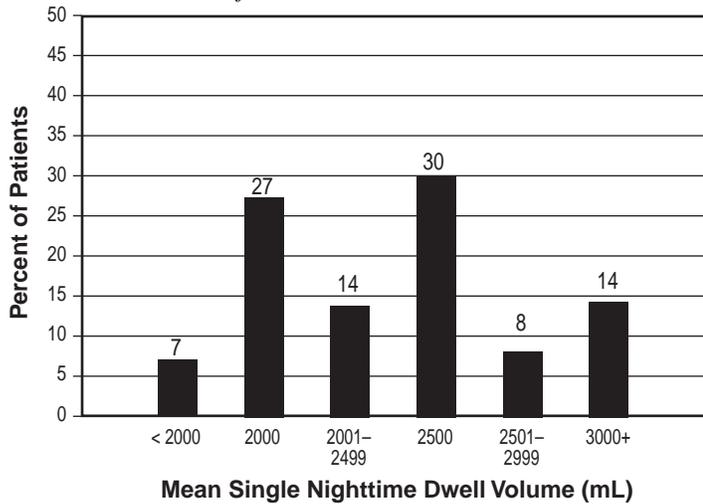
**TABLE 18:** Percent of adult cycler patients with mean ( $\pm$  SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, October 2003–March 2004, 2004 ESRD CPM Project.

Adequacy Measure	Oct 2000–Mar 2001		Oct 2001–Mar 2002		Oct 2002–Mar 2003		Oct 2003–Mar 2004	
	with daytime dwell	no daytime dwell						
<b>Weekly Kt/V<sub>urea</sub></b>								
% meeting NKF-K/DOQI <sup>^</sup>	64%	53%	61%	61%	64%	58%	59%	56%
mean ( $\pm$ SD)	2.33 ( $\pm$ 0.55)	2.33 ( $\pm$ 0.73)	2.33 ( $\pm$ 0.55)	2.39 ( $\pm$ 0.70)	2.31 ( $\pm$ 0.54)	2.53 ( $\pm$ 0.80)	2.29 ( $\pm$ 0.60)	2.39 ( $\pm$ 0.73)
median	2.24	2.22	2.29	2.29	2.25	2.38	2.23	2.30
<b>Weekly Creatinine Clearance (L/week/1.73M<sup>2</sup>)</b>								
% meeting NKF-K/DOQI	55%	61%	53%	53%	49%	56%	48%	44%
mean ( $\pm$ SD)	71.9 ( $\pm$ 25.6)	77.6 ( $\pm$ 31.0)	71.0 ( $\pm$ 26.3)	76.2 ( $\pm$ 31.8)	66.5 ( $\pm$ 22.2)	74.3 ( $\pm$ 33.0)	67.5 ( $\pm$ 24.2)	71.9 ( $\pm$ 30.7)
median	65.7	75.3	65.7	68.1	62.3	70.2	62.5	62.3

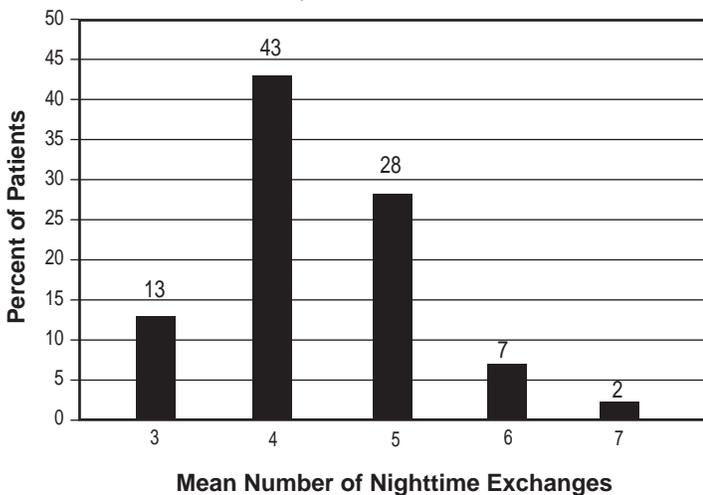
<sup>^</sup> For cycler patients with daytime dwell (CCPD patients): KtV<sub>urea</sub>  $\geq$  2.1; creatinine clearance  $\geq$  63 L/week/1.73m<sup>2</sup>

For nighttime cycler patients (no daytime dwell) (NIPD patients): KtV<sub>urea</sub>  $\geq$  2.2; creatinine clearance  $\geq$  66 L/week/1.73m<sup>2</sup>

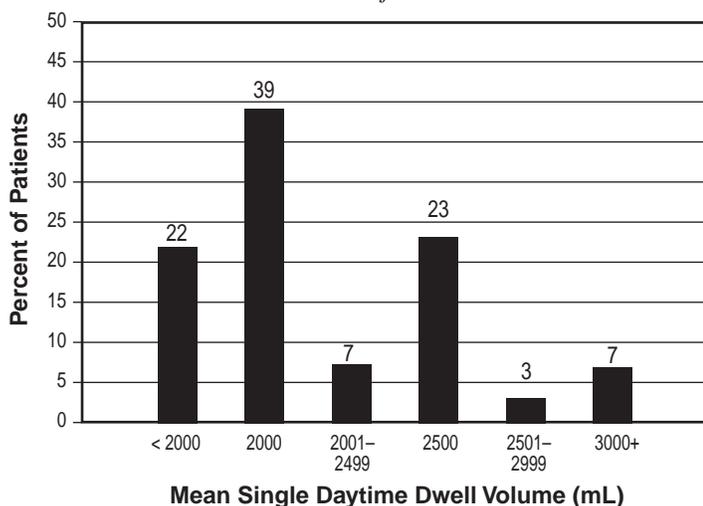
**Figure 48:** Distribution of mean single nighttime dwell volumes for all adultycler patients, October 2003-March 2004. 2004 ESRD CPM Project.



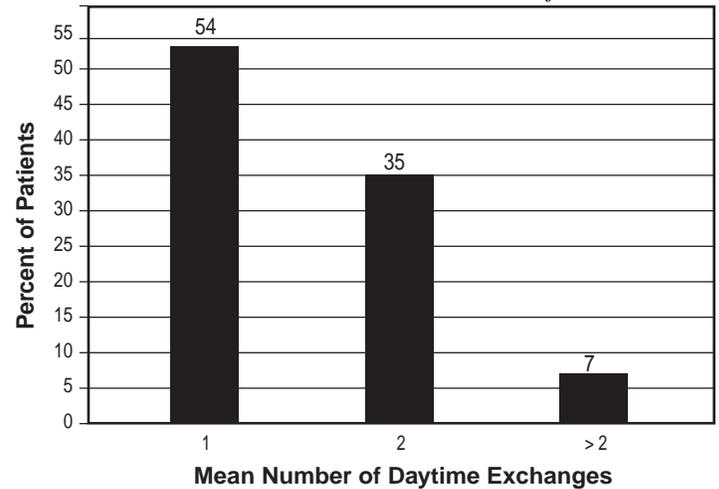
**Figure 49:** Distribution of the mean number of nighttime exchanges for all adultycler patients, October 2003-March 2004. 2004 ESRD CPM Project.



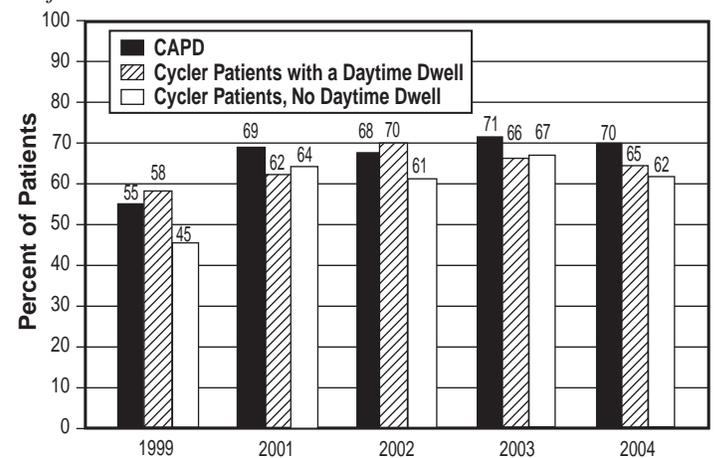
**Figure 50:** Distribution of mean single daytime dwell volumes for adultycler patients with a daytime dwell, October 2003-March 2004. 2004 ESRD CPM Project.



**Figure 51:** Distribution of the mean number of daytime exchanges for adultycler patients with a daytime dwell, October 2003-March 2004. 2004 ESRD CPM Project.



**Figure 52:** Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly  $Kt/V_{urea}$  and weekly creatinine clearance (PD Adequacy CPM III). 2004 ESRD CPM Project.



### 3. CPM and other Findings for October 2003–March 2004 compared to previous study periods

The adequacy of peritoneal dialysis was reported for 86% of adult peritoneal dialysis patients at least once during the 2004 six-month study period, October 2003–March 2004 (PD Adequacy CPM I), compared to 82% during the 1999 study period, 83% during the 2000 study period, 85% during the 2001 study period, 86% during the 2002 study period and 88% during the 2003 study period. (FIGURE 3).

Although the percent of patients meeting NKF-K/DOQI thresholds for peritoneal dialysis adequacy (3) has increased from the 1999 study period, there was little change in the percent of patients meeting these thresholds from the 2001 study period to the 2004 study period (FIGURES 4, 52).

## B. ANEMIA MANAGEMENT

### 1. CPM Findings for October 2003–March 2004

Data to assess three anemia management CPMs were collected in 2004. The time period from which these data were abstracted was October 2003–March 2004.

**Anemia Management CPM I** — The target hemoglobin is 11–12 g/dL (110–120 g/L). Patients with a mean hemoglobin > 12 g/dL (120 g/L) and not prescribed Epoetin were excluded from analysis for this CPM.

**FINDING:** For the six-month study period, 39% of the peritoneal dialysis patients who met the inclusion criteria (n=1,251) had a mean hemoglobin 11–12 g/dL (110–120 g/L) during October 2003–March 2004.

**Anemia Management CPM IIa** — For all anemic patients (hemoglobin < 11 g/dL [110 g/L]) or patients prescribed Epoetin, the percent transferrin saturation and serum ferritin concentration are assessed (measured) at least two times during the six-month study period.

**FINDING:** 79% of the peritoneal dialysis patients who met the inclusion criteria (n=1,237) had at least two documented (measured) transferrin saturation values and at least two documented (measured) serum ferritin concentration values during October 2003–March 2004.

**Anemia Management CPM IIb** — For all anemic patients (hemoglobin < 11 g/dL [110 g/L]) 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:** 83% of the adult peritoneal dialysis patients who met the inclusion criteria (n=1237) had at least one documented transferrin saturation ≥ 20% and at least one documented serum ferritin concentration ≥ 100 ng/mL during October 2003–March 2004.

**Anemia Management CPM III** — All anemic patients (hemoglobin < 11 g/dL [110 g/L]) 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.

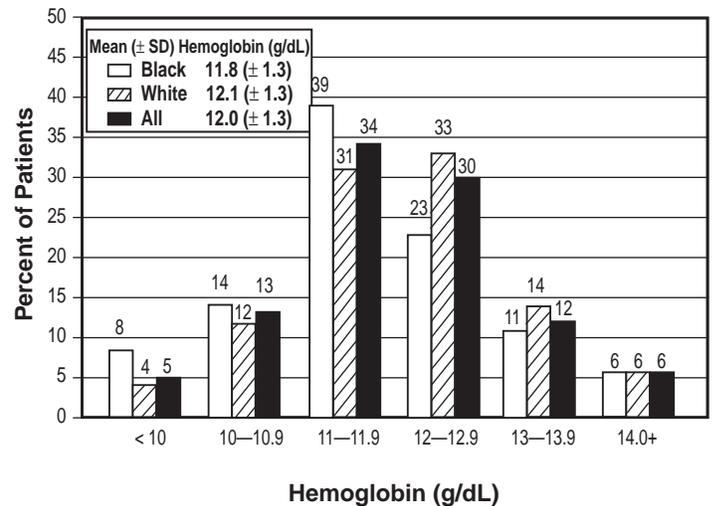
**FINDING:** 29% of the peritoneal dialysis patients who met the inclusion criteria (n=475) were prescribed intravenous iron at least once during October 2003–March 2004.

### 2. Other Anemia Management Findings for October 2003–March 2004

The mean (± SD) hemoglobin for adult peritoneal dialysis patients in the sample was 12.0 (± 1.3) g/dL (120 [± 13] g/L). The distributions of mean hemoglobin values for all patients and by race are depicted in Figure 53. The mean hemoglobin values and the proportion of patients within different hemoglobin categories for gender, race, ethnicity, age, diagnosis, duration of dialysis, mean serum albumin level and weekly creatinine clearance are shown in Table 19. Nationally, 82% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) (FIGURE 8). Significantly more Whites and patients older than 45 years had a mean hemoglobin ≥ 11 g/dL (110 g/L) compared to Blacks, and younger patients (TABLE 19). A larger percentage of patients with higher mean serum albumin and weekly creatinine clearance had a mean hemoglobin ≥ 11 g/dL (110 g/L) compared to patients with lower mean serum albumin and weekly creatinine clearance values. Nationally, 68% of patients prescribed Epoetin had a mean hemoglobin 11–12.9 g/dL (110–129 g/L).

The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was 5% (FIGURE 53, TABLE 19). The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was significantly higher in Blacks compared to Whites, for patients 18–44 years old compared to older patients, and in patients with lower mean serum albumin and creatinine clearance values compared to patients with higher mean serum albumin and creatinine clearance values (TABLE 19).

**Figure 53:** Distribution of mean hemoglobin values for adult peritoneal dialysis patients in the US, by race, October 2003–March 2004. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**TABLE 19:** Mean hemoglobin values (g/dL) for adult peritoneal dialysis patients, by patient characteristics, October 2003-March 2004. 2004 ESRD CPM Project.

Patient Characteristic	Mean hemoglobin (g/dL)	Percent of patients with hemoglobin values					
		< 10	10-10.9	11-11.9	12-12.9	13-13.9	14+
<b>TOTAL</b>	<b>12.0</b>	<b>5</b>	<b>13</b>	<b>34</b>	<b>30</b>	<b>12</b>	<b>6</b>
<b>GENDER</b>							
Men	12.0	5	12	34	31	13	6
Women	12.0	6	14	35	29	12	5
<b>RACE</b>							
American Indian/ Alaska Native	12.0	*	*	*	*	*	*
Asian/Pacific Islander	11.8	*	19	39	25	*	*
Black	11.8	8	14	39	23	11	6
White	12.1	4	12	31	33	14	6
Other/Unknown	12.0	*	*	39	31	*	*
<b>ETHNICITY</b>							
Hispanic	11.9	*	16	33	32	9	*
Non-Hispanic	12.0	5	12	34	30	13	6
<b>AGE GROUP (years)</b>							
18-44	11.8	11	15	35	21	9	9
45-54	12.0	4	14	34	32	11	5
55-64	12.0	*	12	35	32	14	4
65-74	12.2	*	10	32	36	17	4
75+	12.1	*	11	35	31	13	*
<b>CAUSE of ESRD</b>							
Diabetes Mellitus	12.0	4	12	37	29	14	4
Hypertension	12.0	5	14	34	27	12	7
Glomerulonephritis	12.0	*	15	31	34	11	*
Other/Unknown	12.0	7	11	32	31	12	7
<b>DURATION of DIALYSIS (years)</b>							
< 0.5	12.0	*	13	34	24	18	6
0.5-0.9	12.1	6	9	31	34	14	7
1.0-1.9	12.0	4	13	36	29	13	6
2.0-2.9	12.0	*	9	44	28	10	5
3.0-3.9	12.0	*	18	33	29	12	*
4.0+	11.9	8	15	29	33	10	5
<b>MEAN SERUM ALBUMIN (g/dL)</b>							
≥ 3.5/3.2 (BCG/BCP) <sup>^</sup>	12.1	4	11	33	31	13	7
< 3.5/3.2 (BCG/BCP)	11.8	7	16	36	27	11	3
<b>MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m<sup>2</sup>)</b>							
≥60	12.0	3	11	37	30	14	5
<60	11.8	6	15	34	30	9	5

Note: Percentages may not add up to 100% due to rounding.  
<sup>^</sup>BCG/BCP = bromocresol green/bromocresol purple laboratory methods.  
 \*Value suppressed because n ≤ 10.  
 Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

The mean (± SD) transferrin saturation for the patients in this sample was 29.9 (± 10.7)% and 85% of patients had mean transferrin saturation ≥ 20%. The mean (± SD) serum ferritin concentration was 453 (± 405) ng/mL, with 88% of patients having a mean serum ferritin concentration ≥ 100 ng/mL. 48 patients (3% of patients) had both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

88% of the patients in the sample for analysis were prescribed Epoetin during the six-month study period. Epoetin was prescribed 91% of the time when the mean hemoglobin values were < 10 g/dL (100 g/L), 98% of the time when the mean hemoglobin values were between 10-10.9 g/dL (100-109 g/L), 94% of the time when mean hemoglobin values were between 11-11.9 g/dL (110-119 g/L) 92% of the time when mean hemoglobin values were between 12-12.9 g/dL (120-129 g/L), 74% of the time when mean hemoglobin values were between 13-13.9 g/dL (130-139 g/L) and 39% of the time when mean hemoglobin values were 14 g/dL (140 g/L) or greater.

Within the subset of patients who were prescribed Epoetin, 98% were prescribed Epoetin by the SC route; 7% were prescribed Epoetin by the IV route (groups not mutually exclusive). The mean (± SD) weekly Epoetin dose for patients prescribed Epoetin by the SC route was 155.7 (± 163.7) units/kg/week; by the IV route was 177.5 (± 150.1) units/kg/week.

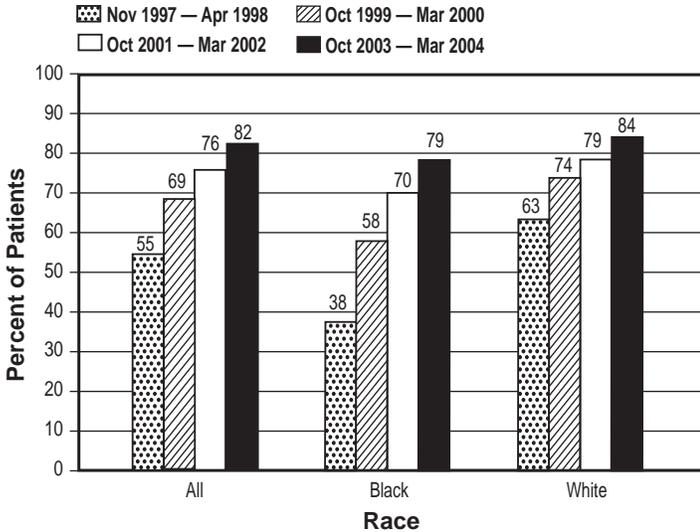
Iron use was assessed during this study period. Iron by either the oral or IV route was prescribed at least once during the six months for 57% of the patients in this sample, and three times over the six-month period for 33% of the patients. Of the patients prescribed iron, 69% were prescribed oral iron and 40% were prescribed IV iron (not mutually exclusive categories). Among those patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL (n=48), 73% were prescribed either oral or IV iron at least once during the six months, and 52% three times over the six-month study period.

### 3. CPM and other Findings for October 2003–March 2004 compared to previous study periods

The percent of peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL (110 g/L) increased from 55% to 82% from the 1998 to the 2004 study periods (FIGURE 8). This improvement was noted for both Black patients (from 38% to 79%) and for White patients (63% to 84%) (FIGURE 54). The percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean hemoglobin < 10 g/dL (100 g/L) decreased from 18% in the 1998 study period to 5% in the 2004 study period. The mean (± SD) hemoglobin increased from 11.9 (± 1.3) g/dL (119 [± 13] g/L) during the 2003 study period to 12.0 (± 1.3) g/dL (120 [± 13] g/L) during the 2004 study period (FIGURE 9). The distribution of mean hemoglobin values over these four study periods was not significantly different by modality (CAPD vs. Cycler).

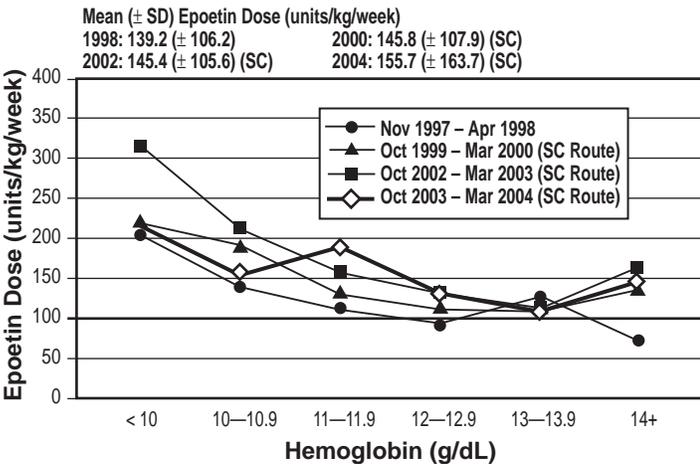
Figure 55 depicts the trend in Epoetin dosing from the 1998 study period to the 2004 study period, with an increasing mean weekly Epoetin dose (units/kg/week) for patients prescribed Epoetin in lower hemoglobin categories. IV doses were generally larger than SC doses (data not displayed due to small cell sizes).

**Figure 54:** Percent of adult peritoneal dialysis patients with mean hemoglobin  $\geq 11$  g/dL, by race, October 2003–March 2004 compared to previous study periods. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 55:** Mean weekly Epoetin dose (units/kg/week) by hemoglobin category for adult peritoneal dialysis patients prescribed Epoetin, October 2003–March 2004 compared to previous study periods. 2004 ESRD CPM Project.



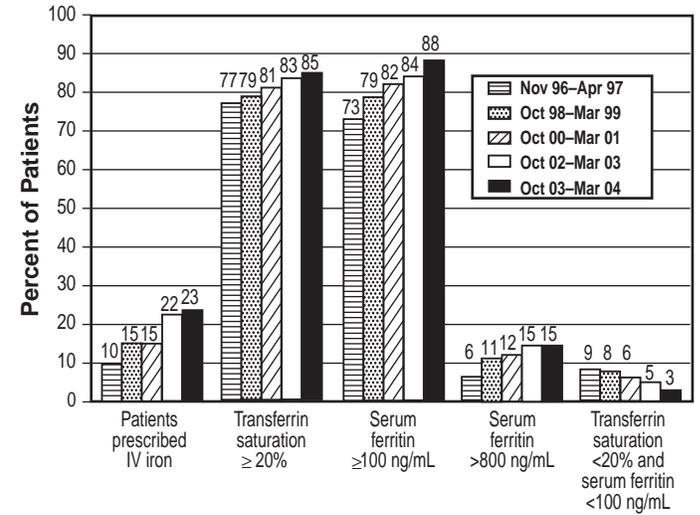
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Note: Route of administration was not collected in 1998.

The distribution of mean transferrin saturation values (%) and mean serum ferritin concentrations (ng/mL) was similar for the November 1996–April 1997 through the October 2003–March 2004 study periods.

Figure 56 depicts the status of iron stores for the sampled patients for study period 2004 compared to selected previous study periods. Overall, 23% of patients were prescribed IV iron during the 2004 study period compared to 10% during the 1997 study period. 3% of patients had a mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL during the 2004 study period compared to 9% during the 1997 study period.

**Figure 56:** Percent of adult peritoneal dialysis patients with specific anemia management indicators, October 2003–March 2004 compared to selected previous study periods. 2004 ESRD CPM Project



### C. SERUM ALBUMIN

#### 1. CPM Findings for October 2003–March 2004

Because serum albumin is not considered to be an official CPM for this project, there are no CPM findings to report for this section.

#### 2. Other Serum Albumin Findings for October 2003–March 2004

The mean ( $\pm$  SD) serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method ( $n=1,267$ ) was  $3.6 (\pm 0.5)$  g/dL ( $36 [\pm 5]$  g/L) and by the BCP method ( $n=109$ ) was  $3.3 (\pm 0.5)$  g/dL ( $33 [\pm 5]$  g/L). A serum albumin of  $\geq 4.0/3.7$  g/dL ( $40/37$  g/L) (BCG/BCP) is the outcome goal. Nationally, 20% of patients had a mean serum albumin  $\geq 4.0/3.7$  g/dL ( $40/37$  g/L) (BCG/BCP). 63% of patients had a mean serum albumin  $\geq 3.5/3.2$  g/dL ( $35/32$  g/L) by the BCG/BCP method (TABLE 20).

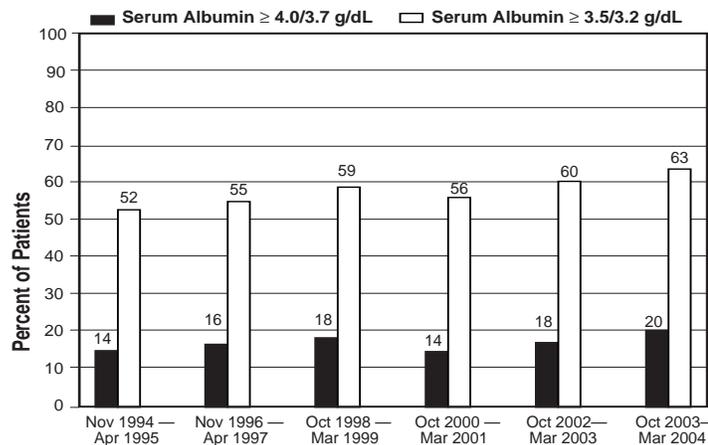
The percent of patients with mean serum albumin values  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) by gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters is shown in Table 20. The percent of patients meeting the mean serum albumin outcome goal tended to be higher for men compared to women, for Hispanics compared to non-Hispanics, for patients 18-44 years compared to older patients, and for patients with causes of their ESRD other than diabetes mellitus compared to patients with diabetes mellitus as the cause (TABLE 20).

### 3. Findings for October 2003–March 2004 compared to previous study periods

Figure 57 shows the percent of patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) and the percent of patients with mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) during the 2004 study period compared to previous study periods.

Although not consistent, there has been slight improvement in the proportion of adult peritoneal dialysis patients achieving a mean serum albumin of  $\geq 4.0/3.7$  g/dL (40/37 g/L) (BCG/BCP) from the 1995 study period to the 2004 study period.

**Figure 57:** Percent of adult peritoneal dialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)\* and  $\geq 3.5/3.2$  g/dL (BCG/BCP), October 2003–March 2004 compared to previous study periods. 2004 ESRD CPM Project.



\*Note: BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**TABLE 20:** Percent of adult peritoneal dialysis patients with mean serum albumin values  $\geq 4.0/3.7$  g/dL (BCG/BCP)<sup>^</sup> and  $\geq 3.5/3.2$  g/dL (BCG/BCP) in the US, by patient characteristics, October 2003–March 2004. 2004 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin	
	$\geq 4.0/3.7$ g/dL	$\geq 3.5/3.2$ g/dL
<b>TOTAL</b>	<b>20</b>	<b>63</b>
<b>GENDER</b>		
Men	22	67
Women	17	59
<b>RACE</b>		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	36	76
Black	20	62
White	18	63
Other/Unknown	29	55
<b>ETHNICITY</b>		
Hispanic	28	68
Non-Hispanic	18	62
<b>AGE GROUP (years)</b>		
18-44	34	75
45-54	20	67
55-64	15	59
65-74	13	55
75+	*	51
<b>CAUSE of ESRD</b>		
Diabetes mellitus	11	53
Hypertension	20	67
Glomerulonephritis	31	69
Other/Unknown	25	70
<b>DURATION of DIALYSIS (years)</b>		
< 0.5	20	63
0.5-0.9	21	69
1.0-1.9	19	61
2.0-2.9	18	61
3.0-3.9	22	65
4.0+	20	62
<b>MEAN Hgb (g/dL)</b>		
$\geq 11$	20	65
< 11	18	52
<b>MEAN WEEKLY CREATININE CLEARANCE (L/week/1.73m<sup>2</sup>)</b>		
$\geq 60$	19	62
< 60	21	67
<b>MODALITY</b>		
CAPD	20	65
Cyclers with daytime dwell	21	64
Cyclers with no daytime dwell	17	62

<sup>^</sup> BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
 \* Value suppressed because n  $\leq 10$ .  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.  
 Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

## VII. PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS

All patients aged < 18 years identified as receiving in-center hemodialysis on December 31, 2003 were included in this study (n=809). 678 patients (84%) of this group met the case definition and were included in the sample for analysis. (See footnote to Table 5 on page 11 for case definition).

At this time, CPMs have not been developed for the pediatric age group. Therefore, the pediatric analysis is presented independently from the adult analysis.

This section describes the findings for pediatric (aged < 18 years) in-center hemodialysis patients for core indicators related to urea clearance, vascular access, anemia management and serum albumin. Each subsection is further broken down into two parts:

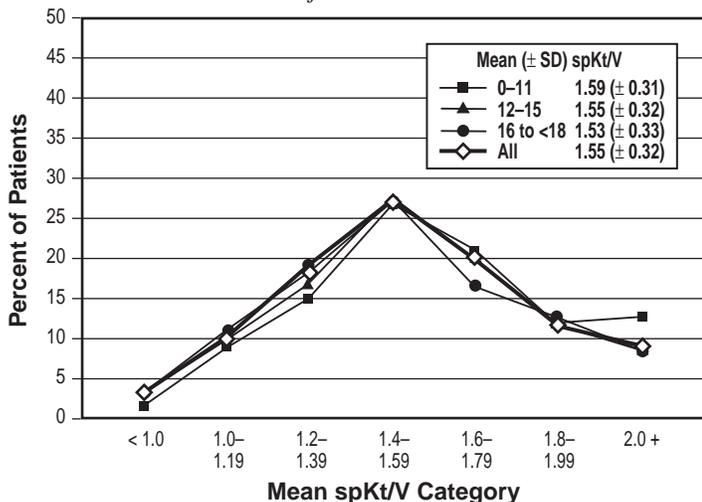
- (1) national findings for selected core indicators for October-December 2003;
- (2) a comparison of core indicator results or findings for October-December 2003 to previous study periods separately for patients 0 to < 12 (n=142) and 12 to < 18 years (n=536).

### A. CLEARANCE

#### 1. Findings for October–December 2003 (for patients < 18 years)

The percent of patients in the sample for analysis with at least one calculated spKt/V measure available (n=653) who had a mean spKt/V  $\geq 1.2$  in the last quarter of 2003 was 86%. The mean ( $\pm$  SD) delivered calculated, single session spKt/V of all pediatric in-center hemodialysis patients in the sample for analysis in the last quarter of 2003 was 1.55 ( $\pm$  0.32) (FIGURE 58). The distribution of spKt/V values for these patients is shown in Figure 58. The spKt/V was calculated using the Daugirdas II method; one blood sample was obtained post-dialysis reflecting a single pool distribution (26). The mean ( $\pm$  SD) delivered calculated URR for this population was 72.0% ( $\pm$  8.0%). 84% of patients had a mean delivered calculated URR  $\geq 65\%$ .

**Figure 58:** Distribution of mean delivered calculated, single session spKt/V values for all pediatric (aged <18 years) in-center hemodialysis patients, by age group, October-December 2003. 2004 ESRD CPM Project.



\*Value suppressed because n  $\leq$  10.

**TABLE 21:** Mean delivered calculated, single session spKt/V for all pediatric (aged < 18 years) in-center hemodialysis patients and percent of patients with mean spKt/V  $\geq 1.2$ , by patient characteristics, October-December 2003. 2004 ESRD CPM Project.

Patient Characteristics	Mean spKt/V	% spKt/V $\geq 1.2$
<b>TOTAL</b>	<b>1.55</b>	<b>86</b>
<b>GENDER</b>		
Males	1.50	84
Females	1.62	88
<b>RACE</b>		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	1.51	85
Black	1.52	85
White	1.58	86
Other/Unknown	1.52	89
<b>ETHNICITY</b>		
Hispanic	1.53	83
Non-Hispanic	1.56	88
<b>AGE GROUP (years)</b>		
0-4	1.56	88
5-9	1.65	91
10-14	1.58	89
15 to <18	1.52	83
<b>DIALYSIS SESSION LENGTH (minutes)</b>		
<180	1.41	68
180-209	1.48	83
210-239	1.61	92
240+	1.68	93
<b>DURATION of DIALYSIS (years)</b>		
< 0.5	1.41	68
0.5-0.9	1.49	85
1.0-1.9	1.57	91
2.0-2.9	1.63	93
3.0-3.9	1.69	97
4.0+	1.64	92
<b>QUINTILE POST-DIALYSIS BODY WEIGHT (kg)</b>		
4.8-30.3	1.64	94
30.4-41.4	1.61	90
41.5-50.0	1.60	92
50.1-61.7	1.51	84
61.8-185.1	1.40	70
<b>ACCESS TYPE</b>		
AV Fistula	1.59	90
AV Graft	1.63	91
Catheter	1.52	83
<b>MEAN Hgb (g/dL)</b>		
$\geq 11$	1.56	89
< 11	1.54	79
<b>MEAN SERUM ALBUMIN (g/dL)</b>		
$\geq 3.5/3.2$ (BCG/BCP) <sup>^</sup>	1.56	88
< 3.5/3.2 (BCG/BCP)	1.51	78

\*Value suppressed because n  $\leq$  10.

<sup>^</sup>BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.  
Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

The mean spKt/V values and the percent of patients with mean spKt/V  $\geq 1.2$ , for all patients by gender, race, ethnicity, age, duration of dialysis, quintile of post-dialysis body weight, access type, and mean hemoglobin and serum albumin categories, are shown in Table 21.

A higher proportion of patients dialyzing six months or longer compared to patients dialyzing less than six months had a mean spKt/V  $\geq 1.2$  (91% vs. 68%), as did patients in the lowest quintile of post-dialysis body weight compared to patients in the highest quintile (94% vs. 70%), patients with dialysis sessions 240 minutes or longer compared to patients with dialysis sessions less than 180 minutes (93% vs. 68%), patients with a mean hemoglobin  $\geq 11$  g/dL compared to patients who did not meet that target (89% vs. 79%), and patients with a mean serum albumin  $\geq 3.5/3.2$  g/dL (35/32 g/L) (BCG/BCP) compared to patients who did not meet that target (88% vs. 78%).

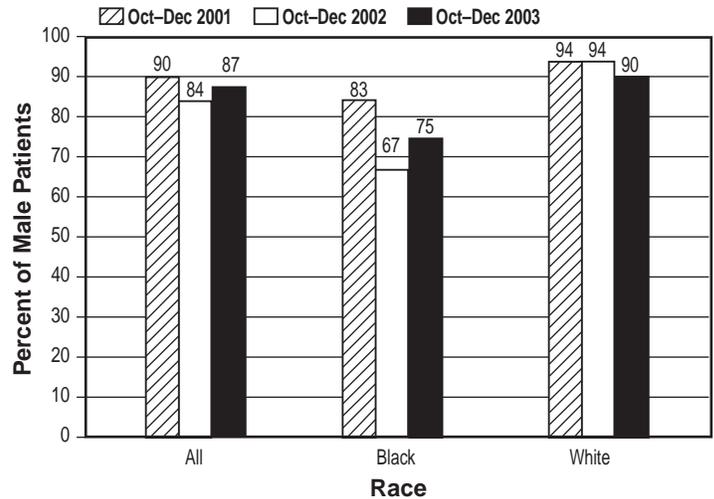
The mean ( $\pm$  SD) time spent on dialysis per dialysis session was 204 ( $\pm$  31) minutes. The mean time spent on dialysis was longer for males compared to females (207 minutes vs. 202 minutes), Blacks compared to Whites (209 minutes vs. 203 minutes), for patients aged 16 to < 18 years compared to patients aged 12 to 15 years and 0 to 11 years (210 minutes vs. 205 and 193 minutes respectively), for patients dialyzing six months or longer compared to patients dialyzing less than six months (207 minutes vs. 196 minutes), for patients in the highest quintile of post-dialysis body weight compared to those patients in the lowest quintile (218 minutes vs. 191 minutes) and for patients dialyzed with an AVF compared to those patients with an AV graft or catheter access (210 minutes vs. 208 minutes and 201 minutes, respectively).

**2. Findings for October-December 2003 compared to previous study periods**

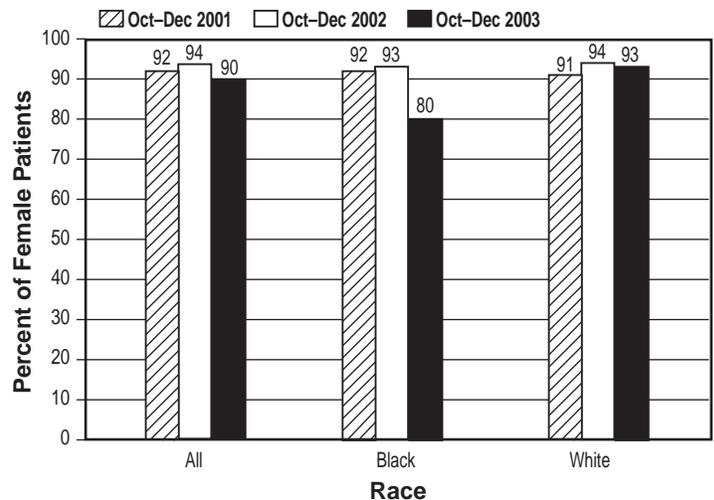
**a. Findings for patients 0 to < 12 years**

The mean ( $\pm$  SD) delivered spKt/V for patients aged 11 years or younger decreased from 1.64 ( $\pm$  0.32) in October-December 2001 to 1.59 ( $\pm$  0.31) in October-December 2003. The percent of these patients receiving dialysis with a mean delivered spKt/V  $\geq 1.2$  decreased from 91% in late 2001 to 88% in late 2003. This decrease occurred for Black and White males and for Black females (FIGURES 59, 60).

**Figure 59:** Percent of all pediatric (aged 0 to < 12 years) male in-center hemodialysis patients with mean delivered calculated, single session spKt/V  $\geq 1.2$ , by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



**Figure 60:** Percent of all pediatric (aged 0 to < 12 years) female in-center hemodialysis patients with mean delivered calculated, single session spKt/V  $\geq 1.2$ , by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.

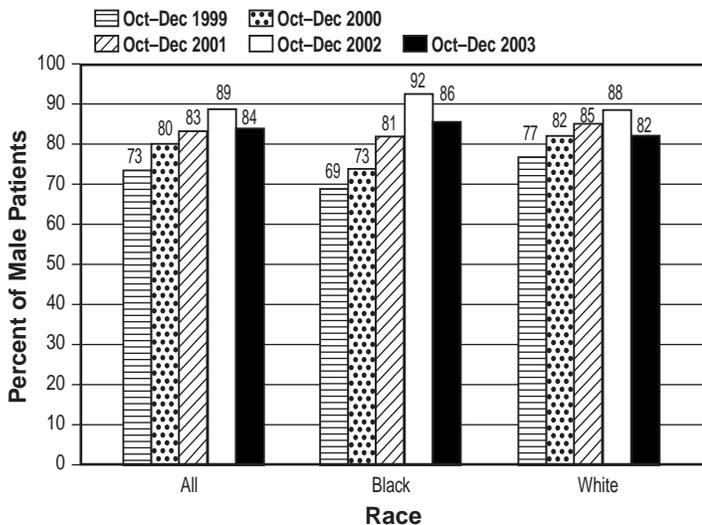


**b. Findings for patients 12 to < 18 years**

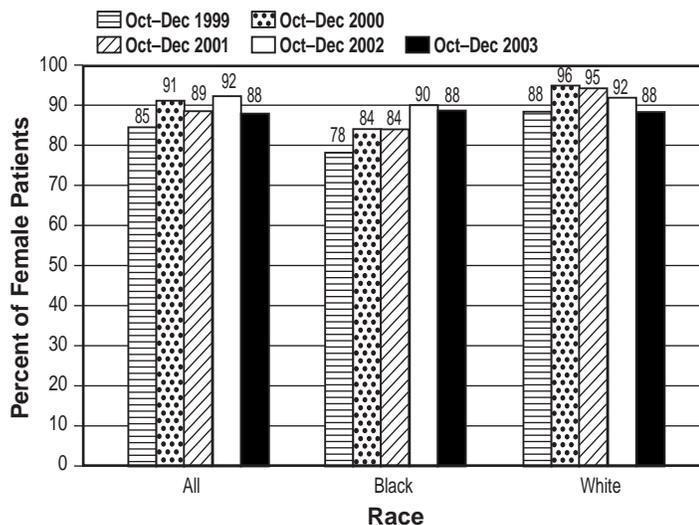
The mean ( $\pm$  SD) delivered spKt/V for patients aged 12 to < 18 years increased from 1.47 ( $\pm$  0.38) in October-December 1999 to 1.54 ( $\pm$  0.32) in October-December 2003. The percent of these patients receiving dialysis with a mean delivered spKt/V  $\geq$  1.2 increased from 79% in late 1999 to 85% in late 2003. This improvement occurred for Black and White males and for Black females (FIGURES 61, 62).

There was very little change in dialysis session length from late 1999 to late 2003.

**Figure 61:** Percent of all pediatric (aged 12 to < 18 years) male in-center hemodialysis patients with mean delivered calculated, single session spKt/V  $\geq$  1.2, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



**Figure 62:** Percent of all pediatric (aged 12 to < 18 years) female in-center hemodialysis patients with mean delivered calculated, single session spKt/V  $\geq$  1.2, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



**B. VASCULAR ACCESS**

**1. Findings for October-December 2003 (for patients < 18 years)**

27% of patients were dialyzed with an AV fistula (AVF), 12% with an AV graft, and 60% with a catheter during October-December 2003 (TABLE 22). The percent of patients with an AVF, AV graft and catheter by selected patient characteristics is shown in Table 22. Opportunities for improvement in the use of AVF exist for all groups, in particular, for patients dialyzing less than six months.

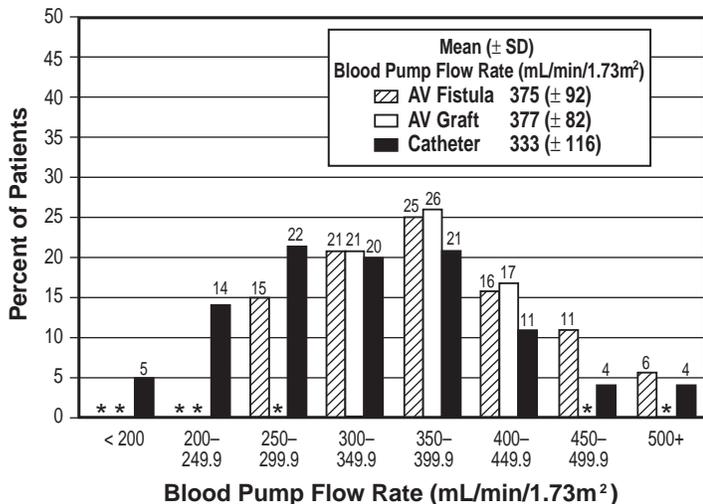
**TABLE 22:** Vascular access type for all pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2003, by selected patient characteristics. 2004 ESRD CPM Project.

Patient Characteristics	Percent of Patients with AV Fistula	AV Graft	Catheter
<b>TOTAL</b>	<b>27</b>	<b>12</b>	<b>60</b>
<b>GENDER</b>			
Males	31	12	58
Females	23	13	64
<b>RACE</b>			
American Indian/ Alaska Native	*	*	*
Asian/Pacific Islander	*	*	90
Black	30	18	52
White	27	9	63
Other/Unknown	23	*	65
<b>ETHNICITY</b>			
Hispanic	27	9	64
Non-Hispanic	28	14	59
<b>AGE GROUP (years)</b>			
0-4	*	*	100
5-9	*	*	90
10-14	23	14	64
15 to <18	36	14	50
<b>DURATION of DIALYSIS (years)</b>			
< 0.5	12	*	86
0.5-0.9	24	10	66
1.0-1.9	34	*	57
2.0-2.9	34	*	53
3.0-3.9	38	*	48
4.0+	32	25	43

NOTE: Percentages may not add up to 100% due to rounding.  
\*Value suppressed because n  $\leq$  10.

The mean ( $\pm$  SD) delivered blood pump flow rate normalized for body surface area (BSA) 60 minutes into the dialysis session was 375 ( $\pm$  92) mL/min/1.73m<sup>2</sup> for patients dialyzed with an AVF, 377 ( $\pm$  82) mL/min/1.73m<sup>2</sup> for patients dialyzed with an AV graft, and 333 ( $\pm$  116) mL/min/1.73m<sup>2</sup> for patients with a catheter access during October-December 2003 (FIGURE 63).

**Figure 63:** Distribution of mean delivered blood pump flow rates normalized for BSA 60 minutes into the dialysis session for all pediatric (aged < 18 years) in-center hemodialysis patients by access type, October-December 2003. 2004 ESRD CPM Project.



\* Values suppressed because n ≤ 10.  
 NOTE: Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (27). This is particularly true for catheters where differences of 25% or more may exist between delivered and prescribed blood flow to the dialyzer at prescribed blood pump flow rates of 400 mL/min or more (28).

408 (60%) patients had a catheter as their current access in late 2003. In patients who had catheters for hemodialysis access, no AVF or AV graft was planned for 45% of the patients, another 29% had no AVF or AV graft created at the end of 2003, and an AVF or AV graft had been created but was not ready to cannulate for 15% (TABLE 23). 3% of patients were not candidates for AVF or AV graft placement as all sites had been exhausted.

**Table 23:** Reasons for catheter placement in all pediatric (aged < 18 years) in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2003. 2004 ESRD CPM Project.

Reason	n (%)
<b>TOTAL</b>	<b>408 (100)</b>
No fistula or graft surgically planned	185 (45)
Patient size too small for AV fistula/graft	82
Patient preference	41
Renal transplantation scheduled	37
Physician preference	39
Peripheral vascular disease	*
No fistula or graft surgically created at this time	120 (29)
Fistula or graft maturing, not ready to cannulate	60 (15)
Temporary interruption of fistula or graft due to clotting or revisions	18 (4)
All fistula or graft sites in this patient's body have been exhausted	12 (3)
Other	13 (3)

NOTE: Percentages may not add up to 100% due to rounding.  
 \*Value suppressed because n ≤ 10.

47% of patients (n=320) were dialyzed with a chronic catheter, defined as the continuous use of a catheter 90 days or longer, during October-December 2003.

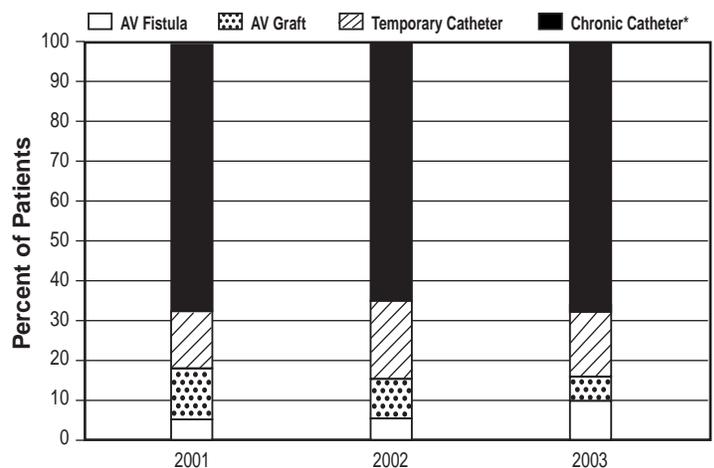
52% of patients (139/267) with an AVF or an AV graft had their access routinely monitored for stenosis. (See Appendix 1 for a complete description of the types of stenosis monitoring). Within this subset of patients, 53% were monitored with dynamic venous pressure, 27% with the dilution technique, 19% with static venous pressure, and 15% had other types of monitoring (groups not mutually exclusive).

## 2. Findings for October-December 2003 compared to previous study periods

### a. Findings for patients 0 to < 12 years

A higher percent of patients aged 11 years or younger was dialyzed with an AVF in late 2003 compared to late 2001 (10% vs. 6%) (FIGURE 64). A higher percent of patients was dialyzed with a catheter in late 2003 compared to late 2001 (83% vs. 80%) (FIGURE 64). There was little change in the percent of patients dialyzed with a chronic catheter for 90 days or longer from late 2001 to late 2003 (68% in 2001 and 69% in 2003).

**Figure 64:** Vascular access type for pediatric (aged 0 to < 12 years) in-center hemodialysis patients on their last hemodialysis session during the study period, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



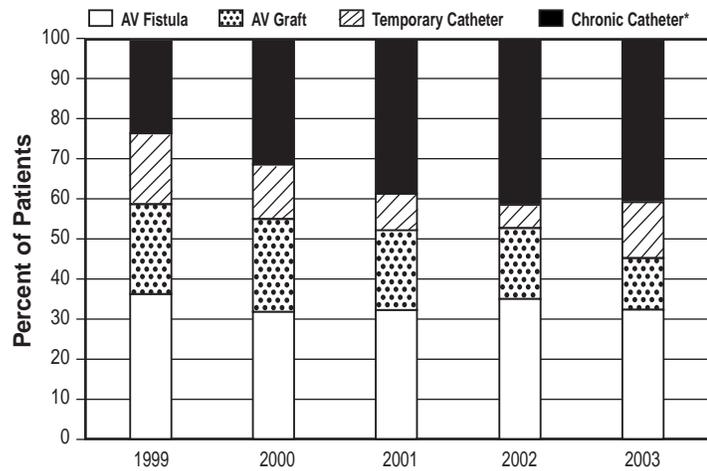
\*Chronic catheter use defined as continuous catheter use 90 days or longer.

**b. Findings for patients 12 to < 18 years**

A lower percent of patients 12 to < 18 years was dialyzed with an AVF in late 2003 compared to late 1999 (32% vs. 37%, respectively) (FIGURE 65). A higher percent of patients was dialyzed with a catheter in late 2003 compared to late 1999 (54% vs. 41%, respectively).

23% of patients were dialyzed with a chronic catheter continuously for 90 days or longer during October-December 1999 and 41% during October-December 2003 (FIGURE 65).

**Figure 65:** Vascular access type for pediatric (aged 12 to < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



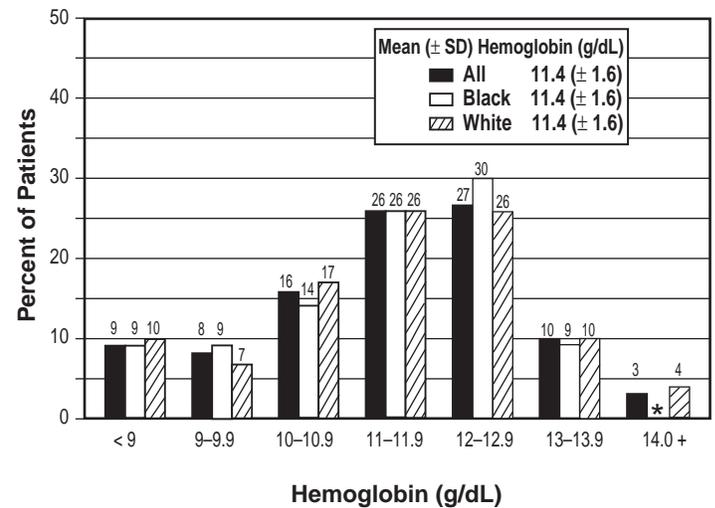
\*Chronic catheter use defined as continuous catheter use 90 days or longer.

**C. ANEMIA MANAGEMENT**

**1. Findings for October-December 2003 (for patients < 18 years)**

The mean hemoglobin for all patients in the sample was 11.4 (± 1.6) g/dL (114 [± 16] g/L) (FIGURE 12). The distributions of mean hemoglobin values for all patients, and by race, are shown in Figure 66. The mean hemoglobin values and distribution of hemoglobin values by gender, race, ethnicity, age, diagnosis, duration of dialysis, access type, and mean spKt/V and serum albumin levels are shown in Table 24.

**Figure 66:** Distribution of mean hemoglobin values (g/dL) for all pediatric (aged < 18 years) in-center hemodialysis patients, by race, October-December 2003. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

The percent of patients with mean hemoglobin < 9 g/dL (90 g/L) was 9%. The percent of patients with mean hemoglobin < 10 g/dL (100 g/L) was 17%. The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was higher in patients dialyzing less than six months compared to those patients dialyzing six months or longer (30% vs. 14%, respectively), and higher in patients with a catheter access compared to patients dialyzed with an AVF or an AV graft (23% vs. 8% and 11%, respectively). A higher percent of patients with a mean serum albumin < 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) compared to patients with higher serum albumin values had a mean hemoglobin < 10 g/dL (100 g/L) (38% vs. 12%).

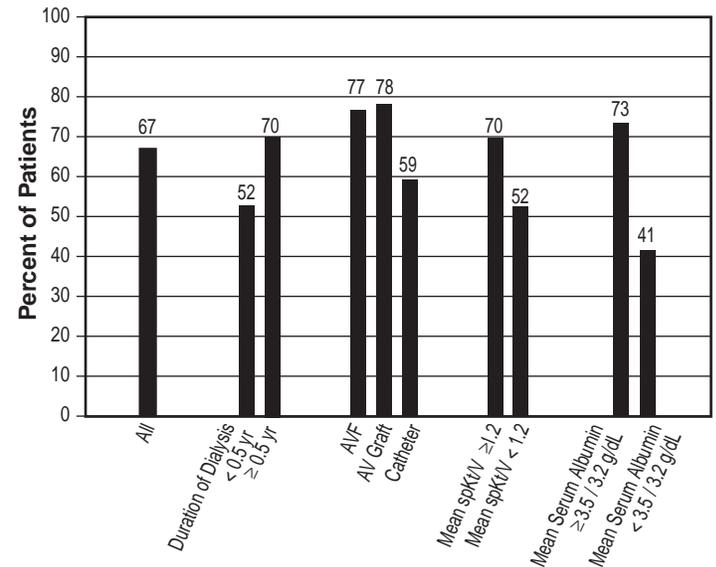
**TABLE 24:** Mean hemoglobin values (g/dL) and distribution of hemoglobin values for all pediatric (aged < 18 years) in-center hemodialysis patients, by patient characteristics, October-December 2003. 2004 ESRD CPM Project.

Patient Characteristic	Mean hemoglobin (g/dL)	Percent of patients with hemoglobin values						
		< 9-9.9	9-9.9	10-10.9	11-11.9	12-12.9	13-13.9	14+
<b>TOTAL</b>	<b>11.4</b>	<b>9</b>	<b>8</b>	<b>16</b>	<b>26</b>	<b>27</b>	<b>10</b>	<b>3</b>
<b>GENDER</b>								
Males	11.5	7	8	16	27	25	12	4
Females	11.2	13	7	16	25	28	9	*
<b>RACE</b>								
American Indian/ Alaska Native	*	*	*	*	*	*	*	*
Asian/Pacific Islander	10.9	*	*	*	*	*	*	*
Black	11.4	9	9	14	26	30	9	*
White	11.4	10	7	17	26	26	10	4
Other/Unknown	11.8	*	*	*	29	*	*	*
<b>ETHNICITY</b>								
Hispanic	11.4	12	5	15	29	24	12	*
Non-Hispanic	11.4	8	9	17	25	28	10	3
<b>AGE GROUP (years)</b>								
0-4	11.0	*	*	*	*	*	*	*
5-9	10.9	*	*	29	25	*	*	*
10-14	11.3	10	11	13	30	23	11	*
15 to < 18	11.6	8	6	15	24	31	11	5
<b>DURATION OF DIALYSIS (years)</b>								
< 0.5	10.9	18	11	18	23	21	8	*
0.5-0.9	11.8	*	*	13	21	33	15	*
1.0-1.9	11.5	*	*	19	25	32	10	*
2.0-2.9	11.8	*	*	15	28	29	*	*
3.0-3.9	11.5	*	*	*	40	30	*	*
4.0+	11.3	8	10	19	30	20	10	*
<b>ACCESS TYPE</b>								
AV Fistula	11.9	*	*	15	25	32	15	*
AV Graft	11.8	*	*	*	26	38	*	*
Catheter	11.1	13	10	18	27	22	9	*
<b>MEAN spKt/V</b>								
≥ 1.2	11.5	7	7	15	27	28	10	4
< 1.2	11.0	18	*	20	22	14	13	*
<b>MEAN SERUM ALBUMIN (g/dL)</b>								
≥ 3.5/3.2 (BCG/BCP) <sup>^</sup>	11.6	7	6	15	28	29	12	4
< 3.5/3.2 (BCG/BCP)	10.5	22	17	21	19	16	*	*

\* Value suppressed because n ≤ 10.  
<sup>^</sup> BCG/BCP = bromocresol green/bromocresol purple laboratory methods.  
 Note: Percentages may not add up to 100% due to rounding.  
 Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

67% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L). The percent of patients with mean hemoglobin ≥ 11 g/dL (110 g/L) by selected patient characteristics is shown in Figure 67.

**Figure 67:** Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by selected patient characteristics and clinical parameters, October-December 2003. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

95% of patients were prescribed Epoetin during the study period. Of the patients prescribed Epoetin, 93% were prescribed Epoetin by the IV route; and 9% by the SC route (groups not mutually exclusive). The mean (± SD) weekly Epoetin dose for patients prescribed Epoetin by the IV route was 368.6 (± 353.6) units/kg/ week; by the SC route, 246.3 (± 249.5) units/kg/week.

The mean (± SD) transferrin saturation for these patients was 28.8 (± 14.2) %. 73% of patients had a mean transferrin saturation ≥ 20%. The mean (± SD) serum ferritin concentration was 440.7 (± 475.2) ng/mL. 78% of patients had a mean serum ferritin concentration ≥ 100 ng/mL. 13% (n=91) of patients had a mean serum ferritin concentration > 800 ng/mL during the study period. 7% (n=46) of patients had a mean transferrin saturation < 20% and a mean serum ferritin < 100 ng/mL.

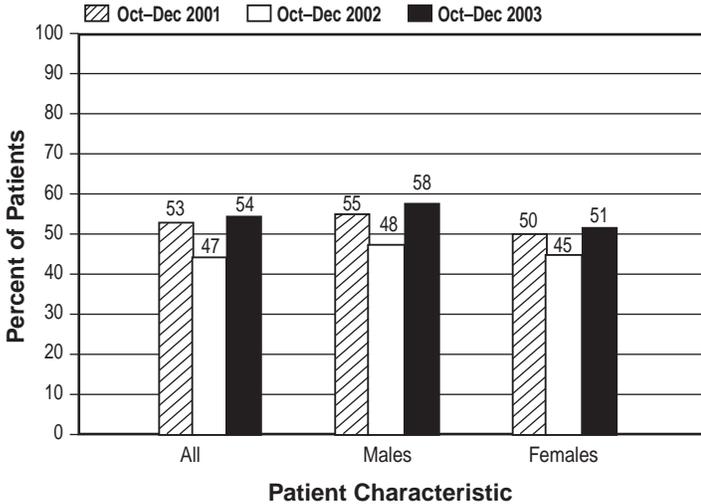
78% of patients were prescribed either IV or oral iron at least once during the three-month study period. The percent of patients with IV iron prescribed was 69%. The mean administered IV iron dose was 251.0 (± 195.3) mg/month. The mean administered IV iron dose per kg per month was 6.24 (± 5.21) mg/kg/month. For the subset of patients with both mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL (n=46 or 7% of patients), only 67% were prescribed IV iron at least once during the three-month study period.

**2. Findings for October-December 2003 compared to previous study periods (for patients < 18 years)**

**a. Findings for patients 0 to < 12 years**

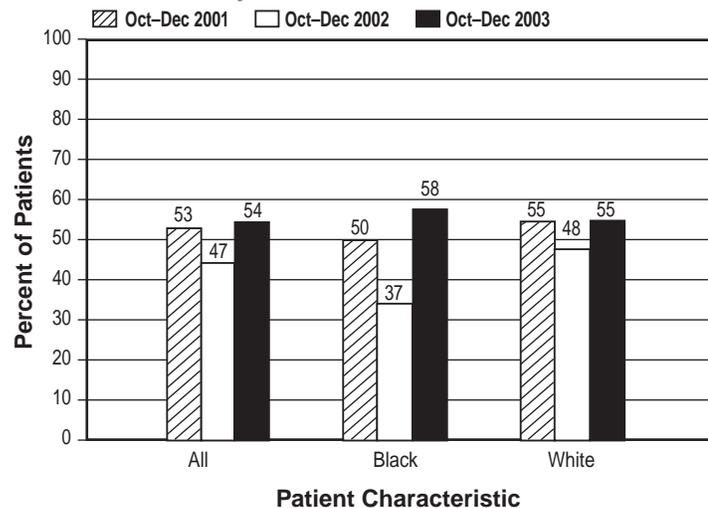
The mean hemoglobin ( $\pm$  SD) for patients aged 11 years or younger remained the same 11.0 ( $\pm$  1.5) g/dL (110 [ $\pm$ 15] g/L) from late 2001 to late 2003. 53% of patients had a mean hemoglobin  $\geq$  11 g/dL (110 g/L) in late 2001 and 54% of patients had a mean hemoglobin  $\geq$  11 g/dL (110 g/L) in late 2003 (FIGURES 68, 69). 21% of patients aged 11 years or younger had a mean hemoglobin < 10g/dL (100 g/L) in late 2003 compared to 24% in late 2001 and 33% in late 2002. Iron management indicators for pediatric patients < 12 years are shown in Figure 70.

**Figure 68:** Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean hemoglobin  $\geq$  11 g/dL, by gender, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



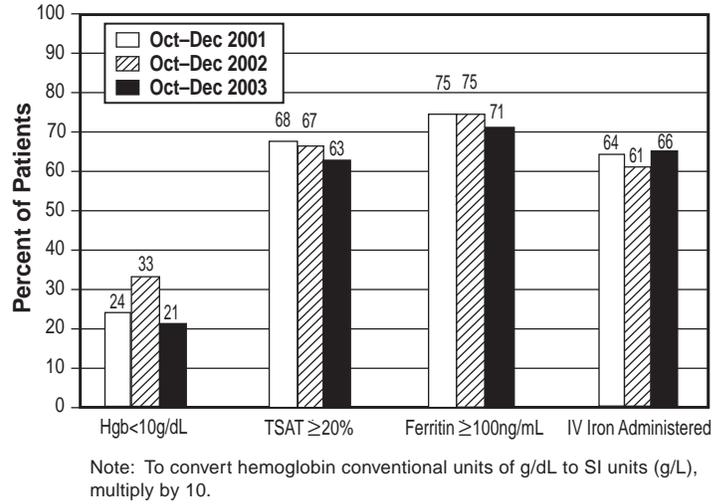
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 69:** Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean hemoglobin  $\geq$  11 g/dL, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 70:** Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with specific anemia management indicators, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.

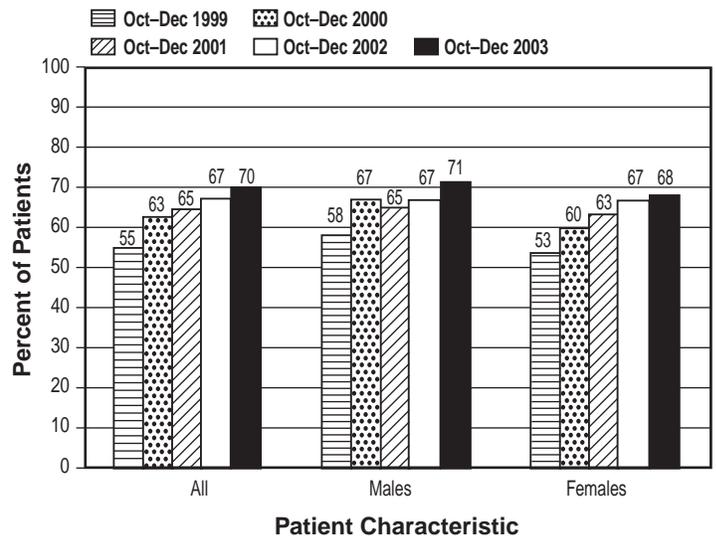


Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**b. Findings for patients 12 to < 18 years**

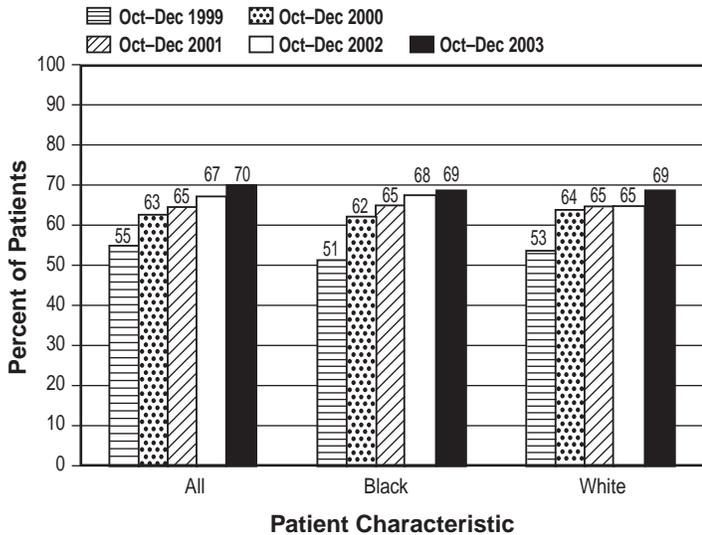
The mean ( $\pm$  SD) hemoglobin from late 1999 to late 2003 for patients 12 to < 18 years increased from 11.0 ( $\pm$  1.6) g/dL (110 [ $\pm$  16] g/L) to 11.5 ( $\pm$ 1.6) g/dL (115 [ $\pm$  16] g/L). The percent of these patients with a mean hemoglobin  $\geq$  11 gm/dL (110 g/L) increased from 55% to 70% (FIGURES 71, 72). This improvement occurred for both male and female patients and for Whites and Blacks (FIGURES 71, 72).

**Figure 71:** Percent of pediatric (aged 12 to < 18 years) in-center hemodialysis patients with mean hemoglobin  $\geq$  11 g/dL, by gender, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**Figure 72:** Percent of pediatric (aged 12 to < 18 years) in-center hemodialysis patients with mean hemoglobin  $\geq 11$  g/dL, by race, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.

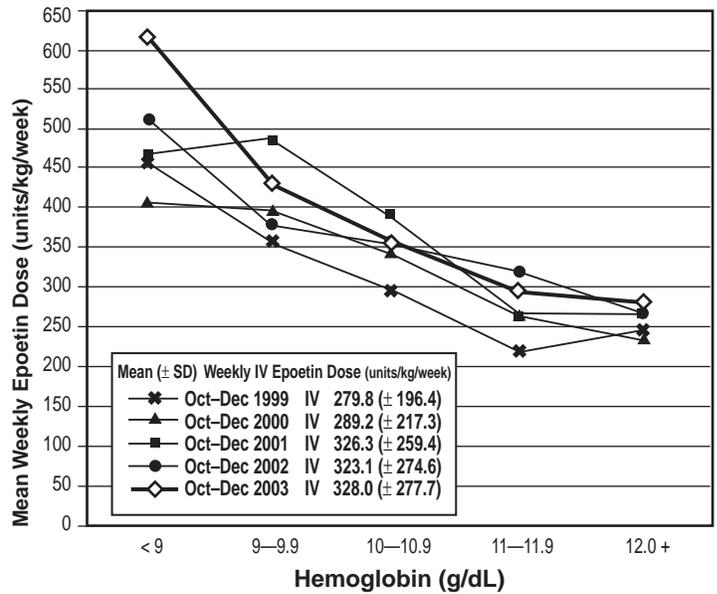


Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

In addition to the improvement in the percent of patients with mean hemoglobin  $\geq 11$  g/dL (110 g/L), there was also a decrease in the percent of patients with mean hemoglobin < 10 g/dL (100 g/L). In October-December 1999, 26% of Black patients and 21% of White patients had a mean hemoglobin < 10 g/dL (100 g/L), while in October-December 2003, 19% of Black patients and 15% of White patients had a mean hemoglobin < 10 g/dL (100 g/L).

Figure 73 depicts the trend for increasing prescribed weekly Epoetin dosing (units/kg/week) from late 1999 to late 2003. Prescribed weekly SC Epoetin doses were lower than the prescribed weekly IV Epoetin doses at most hemoglobin categories examined.

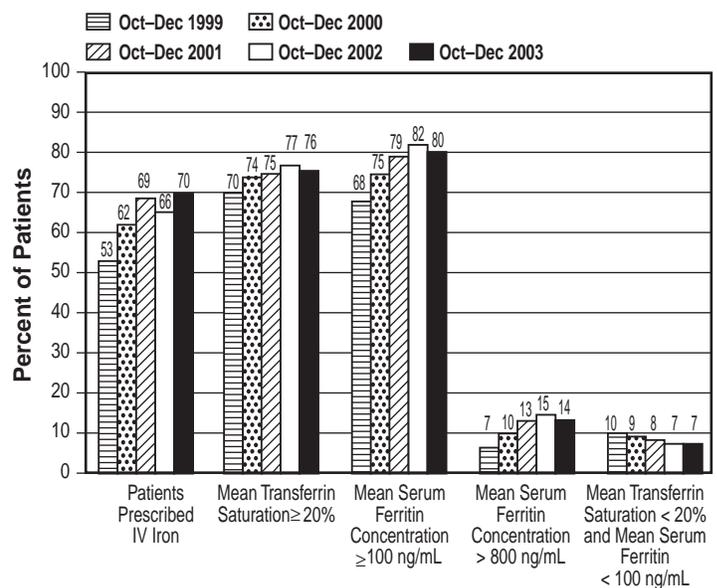
**Figure 73:** Mean prescribed weekly IV Epoetin dose (units/kg/week) for pediatric (aged 12 to < 18 years) in-center hemodialysis patients, by hemoglobin category, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



Note: SC dose distribution not displayed due to small number of patients. Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Iron management for pediatric patients aged 12 to < 18 years improved over the five study periods (FIGURE 74).

**Figure 74:** Iron management parameters for pediatric (aged 12 to < 18 years) in-center hemodialysis patients, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



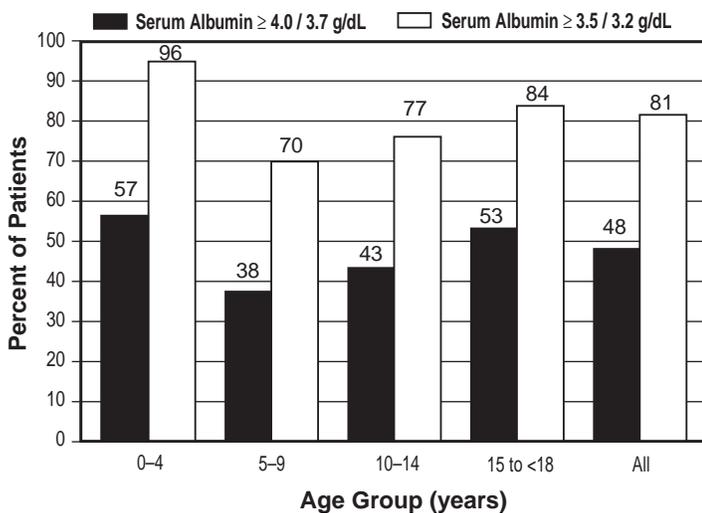
## D. SERUM ALBUMIN

### 1. Findings for October-December 2003 (for patients < 18 years)

The mean ( $\pm$  SD) serum albumin value for pediatric patients whose value was determined by the BCG method (n=566) was 3.9 ( $\pm$  0.5) g/dL (39 [ $\pm$  5] g/L), and by the BCP method (n=112) was 3.6 ( $\pm$  0.4) g/dL (36 [ $\pm$  4] g/L). Nationally, 48% of patients had a mean serum albumin  $\geq$  4.0/3.7 g/dL (40/37 g/L) (BCG/BCP). 81% of patients had a mean serum albumin  $\geq$  3.5/3.2 g/dL (35/32 g/L) (BCG/BCP). The percent of patients with mean serum albumin  $\geq$  4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) by gender, race, ethnicity, age, duration of dialysis, access type, and mean delivered spKt/V and hemoglobin categories is shown in Table 25. The percent of patients with mean serum albumin  $\geq$  4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) tended to be higher for males, Whites, Hispanics, patients dialyzing 6 months or longer compared to patients dialyzing less than 6 months, for patients dialyzed with either an AVF or an AV graft compared to catheters, and for patients with a mean hemoglobin  $\geq$  11 g/dL (110 g/L) compared to patients with lower mean hemoglobin values.

Figure 75 shows the percent of pediatric patients with mean serum albumin  $\geq$  4.0/3.7 g/dL (40/37 g/L) and  $\geq$  3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) by age group.

**Figure 75:** Percent of pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin  $\geq$  4.0/3.7 g/dL (BCG/BCP)<sup>^</sup> and  $\geq$  3.5/3.2 g/dL (BCG/BCP), by age, October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



<sup>^</sup>BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

**TABLE 25:** Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin values  $\geq$  4.0/3.7 g/dL (BCG/BCP)<sup>^</sup>, and  $\geq$  3.5/3.2 g/dL (BCG/BCP), by patient characteristics, October-December 2003. 2004 ESRD CPM Project.

Patient Characteristics	Percent of Patients with Mean Serum Albumin	
	$\geq$ 4.0/3.7 g/dL	$\geq$ 3.5/3.2 g/dL
<b>TOTAL</b>	<b>48</b>	<b>81</b>
<b>GENDER</b>		
Males	54	84
Females	41	77
<b>RACE</b>		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	*	70
Black	41	80
White	53	81
Other/Unknown	50	88
<b>ETHNICITY</b>		
Hispanic	59	85
Non-Hispanic	43	79
<b>AGE GROUP (years)</b>		
0-4	57	96
5-9	38	70
10-14	43	77
15 to < 18	53	84
<b>DURATION of DIALYSIS (years)</b>		
< 0.5	36	65
0.5-0.9	53	80
1.0-1.9	54	87
2.0-2.9	53	85
3.0-3.9	53	90
4.0+	48	86
<b>ACCESS TYPE</b>		
AV Fistula	62	90
AV Graft	56	94
Catheter	41	74
Catheter $\geq$ 90 days	44	79
<b>MEAN spKt/V</b>		
$\geq$ 1.2	50	83
< 1.2	40	70
<b>MEAN Hgb (g/dL)</b>		
$\geq$ 11	57	88
< 11	30	66

NOTE: Percentages may not add up to 100% due to rounding.

\*Value suppressed because n  $\leq$  10.

<sup>^</sup>BCG/BCP = bromcresol green/bromcresol purple laboratory methods.

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

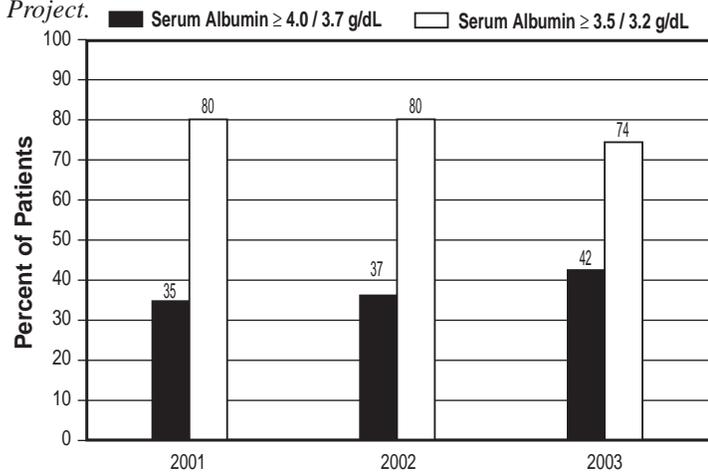
Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

## 2. Findings for October-December 2003 compared to previous study periods (for patients < 18 years)

### a. Findings for patients 0 to < 12 years

There has been little change in the percent of pediatric patients aged 11 years or younger achieving mean serum albumin targets from late 2001 to late 2003 (FIGURE 76).

**Figure 76:** Percent of pediatric (aged 0 to < 12 years) in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)<sup>^</sup> and  $\geq 3.5/3.2$  g/dL (BCG/BCP), October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.

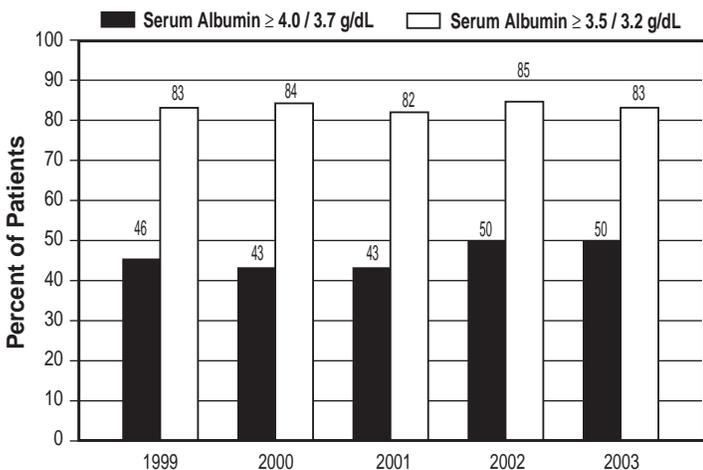


<sup>^</sup>BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

### b. Findings for patients 12 to < 18 years

There was no clinically important change or improvement in the percent of pediatric patients aged 12 to < 18 years achieving mean serum albumin targets from late 1999 to late 2003 (FIGURE 77).

**Figure 77:** Percent of pediatric (aged 12 to < 18 years) in-center hemodialysis patients with mean serum albumin  $\geq 4.0/3.7$  g/dL (BCG/BCP)<sup>^</sup> and  $\geq 3.5/3.2$  g/dL (BCG/BCP), October-December 2003 compared to previous study periods. 2004 ESRD CPM Project.



<sup>^</sup>BCG/BCP = bromcresol green/bromcresol purple laboratory methods.  
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

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## X. Appendices

### Appendix 1. ESRD Clinical Performance Measures (CPMs) for 2004 Data Collection Effort

Study period for HD patients is Oct, Nov, Dec 2003; for PD patients is Oct, Nov, Dec 2003 and Jan, Feb, Mar 2004

#### Hemodialysis (HD) Adequacy

##### 1. HD Adequacy CPM I: Monthly Measurement of Delivered Hemodialysis Dose.

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

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

HD Adequacy Guideline 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:**

Number of patients in denominator with documented monthly adequacy measurements (URR or spKt/V) during the study period. (The study period for HD patients is Oct, Nov, Dec 2003).

**Denominator:**

All adult ( $\geq 18$  years old) HD patients in the sample for analysis.

##### 2. HD Adequacy CPM II: Method of Measurement of Delivered Hemodialysis Dose.

HD Adequacy Guideline 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:**

Number of patients in denominator for whom delivered HD dose was calculated using formal urea kinetic modeling or Daugirdas II during the study period.

**Denominator:**

All adult ( $\geq 18$  years old) HD patients in the sample for analysis.

##### 3. HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose.

HD Adequacy Guideline 4: Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion). The dialysis care team should deliver a spKt/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 spKt/V of 1.2, i.e., an average URR of 65%; however URR can vary substantially as a function of fluid removal.

**Numerator:**

Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form) was a spKt/V  $\geq 1.2$  during the study period.

**Denominator:**

All adult ( $\geq 18$  years old) HD patients in the sample for analysis who have been on HD for six months or more and dialyzing three times per week.

#### Peritoneal Dialysis (PD) Adequacy

##### 4. PD Adequacy CPM I: Measurement of Total Solute Clearance at Regular Intervals.

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

Both total weekly creatinine clearance normalized to 1.73 m<sup>2</sup> body surface area (BSA) and total weekly Kt/V<sub>urea</sub> should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 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  $Kt/V_{urea}$  is  $<0.1$ .

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

**Numerator:**

Number of patients in denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period. (The study period for PD patients is Oct, Nov, Dec 2003 and Jan, Feb, Mar 2004).

**Denominator:**

All adult ( $\geq 18$  years old) PD patients in sample for analysis, excluding tidal dialysis patients.

## 5. PD Adequacy CPM II: Calculate Weekly $Kt/V_{urea}$ and Creatinine Clearance in a Standard Way.

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

Both total weekly creatinine clearance normalized to  $1.73 \text{ m}^2$  body surface area (BSA) and total weekly  $Kt/V_{urea}$  should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 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  $Kt/V_{urea}$  and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance.

PD Adequacy Guideline 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:  $V \text{ (liters)} = 2.447 + 0.3362 \cdot Wt(\text{kg}) + 0.1074 \cdot Ht(\text{cm}) - 0.09516 \cdot \text{Age}(\text{years})$

For Women:  $V = -2.097 + 0.2466 \cdot Wt + 0.1069 \cdot Ht$

Hume method:

For Men:  $V = -14.012934 + 0.296785 \cdot Wt + 0.192786 \cdot Ht$

For Women:  $V = -35.270121 + 0.183809 \cdot Wt + 0.344547 \cdot Ht$

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, Wt is in kg and Ht is in cm:

DuBois and DuBois method:  $BSA \text{ (m}^2\text{)} = 0.007184 \cdot Wt^{0.425} \cdot Ht^{0.725}$

Gehan and George method:  $BSA \text{ (m}^2\text{)} = 0.0235 \cdot Wt^{0.51456} \cdot Ht^{0.42246}$

Haycock method:  $BSA \text{ (m}^2\text{)} = 0.024265 \cdot Wt^{0.5378} \cdot Ht^{0.3964}$

**Numerator:**

The number of patients in denominator with all of the following:

a. Weekly creatinine clearance normalized to  $1.73 \text{ m}^2$  body surface area (BSA) and total weekly  $Kt/V_{urea}$  used to measure delivered PD dose; and

b. Residual renal function (unless negligible\*) is assessed by measuring the renal component of  $Kt/V_{urea}$  and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance; and

c. 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, during the study period.

\* negligible =  $< 200 \text{ mL}$  urine in 24 hours.

**Denominator:**

All adult ( $\geq 18$  years old) PD patients in the sample for analysis, excluding tidal dialysis patients.

## 6. PD Adequacy CPM III: Delivered Dose of Peritoneal Dialysis.

PD Adequacy Guideline 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 (CrCl) of at least  $60 \text{ L/week}/1.73 \text{ m}^2$ .

PD Adequacy Guideline 16: Weekly Dose of NIPD and CCPD (Opinion).

For NIPD, the weekly delivered peritoneal dialysis dose should be a total  $Kt/V_{urea}$  of at least 2.2 and a weekly total CrCl of at least  $66 \text{ L}/1.73 \text{ m}^2$ .

For CCPD, the weekly delivered peritoneal dialysis dose should be a total  $Kt/V_{urea}$  of at least 2.1 and a weekly total CrCl of at least  $63 \text{ L}/1.73 \text{ m}^2$ .

**Numerator:**

a. For CAPD patients in the denominator, the delivered PD dose was a weekly  $Kt/V_{urea}$  of at least 2.0 and a weekly CrCl of at least  $60 \text{ L/week}/1.73 \text{ m}^2$  or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.

b. For cycler patients in the denominator without a daytime dwell (NIPD), the delivered PD dose was a weekly  $Kt/V_{urea}$  of at least 2.2 and a weekly CrCl of at least 66 L/week/1.73 m<sup>2</sup> or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period. For cycler patients in the denominator with a daytime dwell (CCPD), the delivered PD dose was a weekly  $Kt/V_{urea}$  of at least 2.1 and a weekly CrCl of at least 63 L/week/1.73 m<sup>2</sup> or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.

**Denominator:**

All adult ( $\geq 18$  years old) PD patients in the sample for analysis, excluding tidal dialysis patients.

## Vascular Access

### 7. Vascular Access CPM I: Maximizing Placement of Arterial Venous Fistulae (AVF).

Vascular Access Guideline 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:**

- The number of incident patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period. (The study period for HD patients is Oct, Nov, Dec 2003).
- The number of prevalent patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period.

**Denominator:**

- Incident adult ( $\geq 18$  years old) HD patients (defined as those patients initiating their most recent course of HD on or between Jan 1 and Aug 31, 2002) in the sample for analysis.
- Prevalent adult ( $\geq 18$  years old) HD patients in the sample for analysis.

### 8. Vascular Access CPM II: Minimizing Use of Catheters as Chronic Dialysis Access.

Vascular Access Guideline 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:**

The number of patients in the denominator who were dialyzed with a chronic catheter continuously for 90 days or longer prior to the last HD session during the study period.

**Denominator:**

All adult ( $\geq 18$  years old) patients in the sample for analysis.

### 9. Vascular Access CPM III: Monitoring Arterial Venous Grafts for Stenosis

Vascular Access Guideline 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 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:

- Intra-access flow (Evidence)
  - Static venous pressures (Evidence)
  - Dynamic venous pressures (Evidence)
- Other studies or information that can be useful in detecting arterial venous graft stenosis include:
- Measurement of access recirculation using urea concentrations (See Guideline 12) (Evidence)
  - Measurement of recirculation using dilution flow techniques (nonurea-based) (Evidence)
  - Unexplained decreases in the measured amount of hemodialysis delivered (URR,  $Kt/V$ ) (Evidence)
  - 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)
  - Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow (Evidence/Opinion)
  - Doppler ultrasound (Evidence/Opinion)
- Persistent abnormalities in any of these parameters should prompt referral for venography (Evidence).

**Numerator:**

The number of patients in the denominator whose AV graft was routinely monitored (screened) for the presence of stenosis during the study period 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:**

All adult ( $\geq 18$  years old) patients in the sample for analysis who were on HD continuously during the study period and who were dialyzed through an arterial venous graft during their last HD session during the study period.

## Anemia Management

### 10. Anemia Management CPM I: Target Hemoglobin for Epoetin Therapy.

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

The target range for hemoglobin should be 11-12 g/dL (110-120 g/L) (Evidence). This target is for Epoetin therapy and is not an indication for blood transfusion therapy (Opinion).

**Numerator:**

Number of patients in denominator with documented mean Hgb of 11-12 g/dL (110-120 g/L) during the study period. (The study period for HD patients is Oct, Nov, Dec 2002 and Oct, Nov, Dec 2003 and Jan, Feb, Mar 2004 for PD patients).

**Denominator:**

All adult ( $\geq 18$  years old) HD or PD patients in the sample for analysis, exclude patients with mean Hgb  $> 12$  g/dL (120 g/L) who are not prescribed Epoetin at any time during the study period.

### 11. Anemia Management CPM IIa: Assessment of Iron Stores among Anemic Patients or Patients Prescribed Epoetin.

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

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

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

Chronic renal failure patients should have sufficient iron to achieve and maintain a Hgb of 11 to 12 g/dL (110-120 g/L).

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

During the initiation of Epoetin therapy and while increasing the Epoetin dose in order to achieve an increase in hematocrit/hemoglobin, 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 hematocrit/hemoglobin is reached.

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

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

**Numerator:**

a. The number of HD patients in the denominator with at least one documented transferrin saturation and serum ferritin concentration result every three months.

b. The number of PD patients in the denominator with at least two documented transferrin saturation and serum ferritin concentration results over the six-month study period.

[Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

**Denominator:**

a. All adult ( $\geq 18$  years old) HD patients included in the sample for analysis, if first monthly Hgb is  $< 11$  g/dL (110 g/L) for at least one of the study months or if prescribed Epoetin at any time during the study period regardless of Hgb.

b. All adult ( $\geq 18$  years old) PD patients included in the sample for analysis, if first monthly Hgb is  $< 11$  g/dL (110 g/L) for at least one of the two-month periods during the six-month study period or if prescribed Epoetin at any time during the study period regardless of Hgb.

### 12. Anemia Management CPM IIb: Maintenance of Iron Stores-Target.

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

To achieve and maintain target Hgb of 11-12 g/dL (110-120 g/L), sufficient iron should be administered to maintain a transferrin saturation of  $\geq 20\%$ , and a serum ferritin concentration of  $\geq 100$  ng/mL.

**Numerator:**

a. The number of HD patients in the denominator with at least one documented transferrin saturation  $\geq 20\%$  and at least one documented serum ferritin concentration  $\geq 100$  ng/mL during a three-month period.

b. The number of PD patients in the denominator with at least one documented transferrin saturation  $\geq 20\%$  and at least one documented serum ferritin concentration  $\geq 100$  ng/mL during the six-month study period.

[Note: Not directly comparable to Numerator “a”, but most feasible given probable frequency of visits for PD patients.]

**Denominator:**

a. All adult ( $\geq 18$  years old) HD patients included in sample, if first monthly Hgb is  $< 11$  g/dL (110 g/L) for at least one of the study months or if prescribed Epoetin at any time during the study period regardless of Hgb.

b. All adult ( $\geq 18$  years old) PD patients included in sample, if first monthly Hgb is  $< 11$  g/dL (110 g/L) for at least one of the two-month periods during the six-month study period or if prescribed Epoetin at any time during the study period regardless of Hgb.

### 13. Anemia management CPM III: Administration of Supplemental Iron.

Anemia Management Guideline 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 Hgb of 11 to 12 g/dL (110-120 g/L) in conjunction with Epoetin therapy.

Anemia Management Guideline 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 Guideline 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  $> 20\%$ , serum ferritin concentration  $> 100$  ng/mL, and Hgb at 11-12 g/dL (110-120 g/L).

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

Most patients will achieve a Hgb 11 to 12 g/dL (110-120 g/L) with transferrin saturation and serum ferritin concentration  $< 50\%$  and  $< 800$  ng/mL, respectively. In patients in whom transferrin saturation is  $50\%$  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  $50\%$  and 800 ng/mL, respectively, intravenous iron can be resumed at a dose reduced by one-third to one-half.

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

It is anticipated that once optimal hematocrit/hemoglobin 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 hematocrit/hemoglobin 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:**

a. The number of HD patients in the denominator prescribed intravenous iron in at least one of the study months.

b. The number of PD patients in denominator prescribed intravenous iron in at least one of the two-month periods during the six-month study period

**Denominator:**

a. All adult ( $\geq 18$  years old) HD patients included in the sample for analysis if first monthly Hgb  $< 11$  g/dL (110 g/L) for at least one month out of a three-month period or prescribed Epoetin at any time during the study period regardless of Hgb level, with at least one transferrin saturation  $< 20\%$  or at least one serum ferritin concentration  $< 100$  ng/mL. EXCLUDE patients with mean transferrin saturation  $\geq 50\%$  or mean serum ferritin concentration  $\geq 800$  ng/mL and EXCLUDE patients in first three months of dialysis and prescribed oral iron.

b. All adult ( $\geq 18$  years old) PD patients included in the sample for analysis if the first Hgb in a two-month period  $< 11$  g/dL (110 g/L) for at least one of the two-month periods during the six-month study period or prescribed Epoetin at any time during the study period regardless of Hgb level, with at least one transferrin saturation  $< 20\%$  or at least one serum ferritin concentration  $< 100$  ng/mL. EXCLUDE patients with mean transferrin saturation  $\geq 50\%$  or mean serum ferritin concentration  $\geq 800$  ng/mL and EXCLUDE patients in first three months of dialysis and prescribed oral iron.



IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)			
18. ANEMIA MANAGEMENT: For each lab question below, enter the lab value obtained from the monthly lab draw for each month: OCT, NOV, DEC 2003. Enter NF/NP if the lab value cannot be located.			
	OCT 2003	NOV 2003	DEC 2003
A. Pre-dialysis laboratory hemoglobin (Hgb) from the monthly lab draw:	_____ . _____ g/dL (If NF/NP go to 18C)	_____ . _____ g/dL (If NF/NP go to 18C)	_____ . _____ g/dL (If NF/NP go to 18C)
B.1.a. Did the patient receive Epoetin at any time during the 30 days before the Hgb in 18A was drawn?	Epoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
B.1.b. Did the patient receive Darbepoetin (Aranesp™) at any time during the 30 days before the Hgb in 18A was drawn?	Darbepoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
B.2.a. What was the PRESCRIBED Epoetin dose in units for each treatment during the 7 days immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 4)	Epoetin: _____ _____ _____ units/tx	Epoetin: _____ _____ _____ units/tx	Epoetin: _____ _____ _____ units/tx
B.2.b. What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 4)	Darbepoetin: _____ mcg/month	Darbepoetin: _____ mcg/month	Darbepoetin: _____ mcg/month
B.3. a. How many times per week was Epoetin prescribed? Check box if prescribed < 1 x per week.	Epoetin: _____ x per week <input type="checkbox"/> < 1 x per week	Epoetin: _____ x per week <input type="checkbox"/> < 1 x per week	Epoetin: _____ x per week <input type="checkbox"/> < 1 x per week
B.3.b. How many times per month was Darbepoetin prescribed?	Darbepoetin: _____ x per month	Darbepoetin: _____ x per month	Darbepoetin: _____ x per month
B.4. a. What was the prescribed route of administration for Epoetin? (Check all that apply)	Epoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown
B.4.b. What was the prescribed route of administration for Darbepoetin? (Check all that apply)	Darbepoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown
C. Serum ferritin concentration from the monthly lab draw:	_____ ng/mL	_____ ng/mL	_____ ng/mL
D. % transferrin (iron) saturation from the monthly lab draw:	_____ %	_____ %	_____ %
E. Was iron prescribed at any time during the month?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19) <input type="checkbox"/> Unknown (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19) <input type="checkbox"/> Unknown (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19) <input type="checkbox"/> Unknown (go to 19)
F. If yes, what was the prescribed route of iron administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> PO <input type="checkbox"/> Unknown	<input type="checkbox"/> IV <input type="checkbox"/> PO <input type="checkbox"/> Unknown	<input type="checkbox"/> IV <input type="checkbox"/> PO <input type="checkbox"/> Unknown
G. If the patient was prescribed IV iron, what was the total dose of IV iron administered during the month?	_____ mg/month	_____ mg/month	_____ mg/month

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)			
<b>19. SERUM ALBUMIN:</b> Enter the serum albumin obtained from the monthly lab draw for each month: OCT, NOV and DEC 2003. Enter NF/NP if the lab value cannot be located. Check the method used (BCG/bromcresol green or BCP/bromcresol purple) by the lab to determine serum albumin. If lab method unknown, please call lab to find out.			
	OCT 2003	NOV 2003	DEC 2003
A. Serum albumin from the monthly lab draw:	_____ . _____ g/dL	_____ . _____ g/dL	_____ . _____ g/dL
B. Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP
<b>20. ADEQUACY:</b> Enter the information requested below for the dialysis session when the monthly labs were drawn and used to measure adequacy for each month: OCT, NOV, DEC 2003. Enter NF/NP if the information cannot be located.			
	OCT 2003	NOV 2003	DEC 2003
A. How many times per week was this patient prescribed to receive dialysis?	_____ times per week	_____ times per week	_____ times per week
B. Recorded URR from the monthly lab draw:	_____ . _____ %	_____ . _____ %	_____ . _____ %
C. Recorded single-pool Kt/V from the monthly lab draw:	_____ . _____	_____ . _____	_____ . _____
D. Method used to calculate the single-pool Kt/V in 20C: (If unknown, please ask Medical Director)	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Depner <input type="checkbox"/> Derived from URR based on no pt. wts. <input type="checkbox"/> Other _____	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Depner <input type="checkbox"/> Derived from URR based on no pt. wts. <input type="checkbox"/> Other _____	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Depner <input type="checkbox"/> Derived from URR based on no pt. wts. <input type="checkbox"/> Other _____
E. Was residual renal function used to calculate the single-pool Kt/V in 20C on this patient?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
F. Pre-dialysis BUN value from the monthly lab draw:	_____ mg/dL	_____ mg/dL	_____ mg/dL
G. Post-dialysis BUN value from the monthly lab draw: (both the pre & post dialysis BUN must be drawn on the same day)	_____ mg/dL	_____ mg/dL	_____ mg/dL
H. Pre- & Post-dialysis weight at session when BUNs above drawn: (Circle either lbs or kgs)	Pre: _____ . _____ lbs/kgs Post: _____ . _____ lbs/kgs	Pre: _____ . _____ lbs/kgs Post: _____ . _____ lbs/kgs	Pre: _____ . _____ lbs/kgs Post: _____ . _____ lbs/kgs
I. Actual DELIVERED time on dialysis at session when BUNs above drawn:	_____ hrs _____ min	_____ hrs _____ min	_____ hrs _____ min
J. Delivered blood pump flow rate @ 60 minutes after start of dialysis session when BUNs above drawn:	_____ mL/min	_____ mL/min	_____ mL/min
K. Code for dialyzer used for dialysis session when BUNs above drawn: (see chart)	_____	_____	_____

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)	
<p><b>21. VASCULAR ACCESS: What type of access was used on the last hemodialysis session on or between 10/1/2003 and 12/31/2003 at the patient's primary in-center facility? Check only one of the following access types and follow the corresponding directions.</b></p>	
<input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft  If you checked AV Fistula or Synthetic or Bovine Graft, please answer questions 1 and 2 at the right.	<p>1. Was routine surveillance for the presence of stenosis performed between 10/1/03 and 12/31/03?  <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p> <p>2. If answer to question 1 is "Yes," please check all methods of surveillance (below) that were utilized. (See instructions on page 6).  <input type="checkbox"/> Color-Flow Doppler at least once between 10/1/03 and 12/31/03  <input type="checkbox"/> Static Venous Pressure at least once every 2 weeks between 10/1/03 and 12/31/03  <input type="checkbox"/> Dynamic Venous Pressure every HD session between 10/1/03 and 12/31/03  <input type="checkbox"/> Dilution Technique at least once between 10/1/03 and 12/31/03  <input type="checkbox"/> Other _____</p>
<input type="checkbox"/> Catheter <input type="checkbox"/> Port Access  If you checked Catheter or Port Access, please answer questions 1 and 2 at the right.	<p>1. Reason for catheter or port access:  <input type="checkbox"/> Fistula or graft maturing, not ready to cannulate  <input type="checkbox"/> Temporary interruption of fistula or graft due to clotting or revisions  <input type="checkbox"/> All fistula or graft sites have been exhausted  <input type="checkbox"/> No fistula or graft surgically created at this time</p> <p><input type="checkbox"/> No fistula or graft surgically planned (check all that apply)  <input type="radio"/> Peripheral vascular disease  <input type="radio"/> Patient size too small for AV fistula or graft  <input type="radio"/> Renal transplantation scheduled  <input type="radio"/> Patient preference  <input type="radio"/> Physician/Surgeon preference  <input type="checkbox"/> Other _____</p> <p>2. Had a catheter or port access been used exclusively for the past 90 days or longer?  <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>
<input type="checkbox"/> Unknown	
<p><b>22. Did the patient FIRST start hemodialysis during January 1, 2003-August 31, 2003 (see date #8 on page 1)? DO NOT include patients who transferred from peritoneal dialysis, had a newly failed transplant, or returned after an episode of regained kidney function (See instructions on page 6). <input type="checkbox"/> Yes (answer 22A-B) <input type="checkbox"/> No</b></p>	
<p>A. What type of access was in use at the <b>Initiation</b> of a maintenance course of hemodialysis (See date #8 on page 1)?  <input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Port Access <input type="checkbox"/> Unknown</p>	
<p>B. What type of access was in use 90 days later?  <input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Port Access <input type="checkbox"/> Unknown</p>	
<p><b>INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 22 (Continued from page 1): To answer questions 18 through 22, review the patient's clinic or facility medical record for OCT 1, 2003 through DEC 31, 2003. Do not leave any items blank. Enter NF/NP if the information cannot be located.</b></p>	
<p><b>18A:</b> Enter the patient's pre-dialysis hemoglobin (Hgb) from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If not found or not performed during the month, enter NF/NP.</p>	
<p><b>18B.1:</b> Check the appropriate box to indicate if the patient received EPOETIN at anytime during the 30 days BEFORE the date of the hemoglobin in 18A or for DARBEPOETIN (Aranesp™) at anytime during the 30 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to question 18C.</p>	
<p><b>18.B.2:</b> If <b>Epoetin</b> was prescribed, enter the PRESCRIBED Epoetin dose, <b>not the administered dose</b>, in units given at each dialysis treatment during the 7 days immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a treatment, etc. Enter "0" if the patient was on "Hold" for a treatment. (For the purposes of this collection, a "Hold" order will be considered a 0 unit prescribed dose.) If Epoetin is prescribed less frequently than every dialysis treatment, leave the unit/tx space blank to indicate one or two doses per the 7-day period.</p> <p>If <b>Darbepoetin</b> (Aranesp™) was prescribed, enter the PRESCRIBED MONTHLY Darbepoetin dose, <b>not the administered dose</b>, in micrograms per month during the month immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a treatment, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 mcg/month prescribed dose.)</p>	
<p><b>18.B.3:</b> Enter the number of times per week that Epoetin was prescribed (check the box if Epoetin was prescribed less than once per week) OR the number of times per month Darbepoetin was prescribed.</p>	

<b>IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)</b>
<b>18B.4:</b> Check the appropriate box to indicate the prescribed route of administration for Epoetin or for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient was prescribed Epoetin or Darbepoetin IV and SC during the month, please check both boxes.
<b>18C:</b> Enter the patient's serum ferritin concentration from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a serum ferritin concentration test was not found or not performed during the month, enter NF/NP.
<b>18D:</b> Enter the patient's % transferrin (iron) saturation from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a % transferrin (iron) saturation test was not found or not performed during the month, enter NF/NP.
<b>18E:</b> Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 2003. If there was no prescription for iron go to question 19.
<b>18F:</b> If the answer to 18E is "Yes", please check the appropriate box to indicate the route of iron administration (intravenous [IV] or by mouth [PO]) for OCT, NOV, and DEC 2003. If the patient received iron by mouth <b>and</b> IV during the month please check both boxes.
<b>18G:</b> If the patient was prescribed IV iron, add together all doses that were given during the month and enter the TOTAL dose of IV iron (in mg) administered per month during OCT, NOV, and DEC 2003.
<b>19A:</b> Enter the patient's serum albumin from the monthly lab draw (or first time during the month if not done with the monthly lab draw) for each month OCT, NOV, DEC 2003. If a serum albumin was not found or not performed during the month, enter NF/NP.
<b>19B:</b> Check the method used by the laboratory to determine the serum albumin value (bromcresol green or bromcresol purple). If you do not know what method the laboratory used, call the lab to find out this information.
<b>20A:</b> Enter the number of times per week the patient was <b>prescribed</b> to receive dialysis in OCT, NOV, and DEC 2003. If the prescription varied during a month, enter the prescription in effect the week the monthly labs were drawn. Do not leave this question blank.
<b>20B:</b> Enter the patient's URR recorded on the lab sheet from the monthly lab draw for each month OCT, NOV, DEC 2003. If not found or not performed during a month, enter NF/NP.
<b>20C:</b> Enter the patient's single-pool Kt/V recorded on the lab sheet from the monthly lab draw for each month OCT, NOV, DEC 2003. If not found or not performed during a month, enter NF/NP.
<b>20D:</b> Check the box to indicate the method used to calculate the single-pool Kt/V in 20C. If you do not know what method was used, please ask the unit's Medical Director. Please check the "Other" box if you do not use any of the methods listed. If using another method and you know what it is, please write the method in the space provided.
<b>20E:</b> Check the appropriate box to indicate whether residual renal function was used to calculate the single-pool Kt/V in 20C. If you do not know, please ask the unit's Medical Director.
<b>20F &amp; G:</b> Enter the patient's pre- and post-dialysis BUNs from the monthly lab draw (or the BUNs used to measure adequacy for the month, if there was a blood drawing error when the monthly labs were drawn). Enter NF/NP if not found or not performed during the month.
<b>20H:</b> Enter the patient's pre- and post-dialysis weight at the dialysis session when the pre- and post-dialysis BUNs in question 20F&G were drawn. Circle either lbs or kgs as appropriate.
<b>20I:</b> Enter the patient's total treatment time (actual delivered time) on dialysis during the session when the BUNs in question 20F&G were drawn for months OCT, NOV, DEC 2003. Do not enter the prescribed time on dialysis.
<b>20J:</b> Enter the delivered blood pump flow rate in mL/minutes at 60 minutes after the start of the dialysis session when the BUNs in questions 20F&G were drawn for months OCT, NOV, DEC 2003. Do not enter the prescribed blood pump flow rate or the highest achieved blood pump flow rate.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)
<p><b>20K:</b> Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used at the dialysis session when the pre- and post-dialysis BUNs in question 20F&amp;G were drawn for OCT, NOV, DEC 2003. If the dialyzer used is not listed on the chart, enter the code for “other” (9999).</p>
<p><b>21:</b> Check only one type of vascular access used on <b>last hemodialysis session on or between OCT 1, 2003 and DEC 31, 2003</b> at the patient’s primary in-center facility and then complete the corresponding questions to the right of the access type. Exclude dialysis sessions performed at temporary facilities because of holiday travel or hospitalizations. (“Port Access” is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).</p>
<p><b>AV Fistula, Synthetic Graft, Bovine Graft:</b> If the vascular access marked for question 21 was an AV fistula, synthetic graft or bovine graft, indicate if routine surveillance for the presence of stenosis between Oct 1, 2003 and Dec 31, 2003 was done. Routine surveillance is the sequential measurement of access flow OR of venous pressure.</p> <ul style="list-style-type: none"> <li>• Indicate “<b>YES</b>” for this question if you measure access flow OR venous pressure using any of the following: <ul style="list-style-type: none"> <li>Techniques and frequencies used to measure access flow include: <ul style="list-style-type: none"> <li>a. one of the dilution methods in which the needles are reversed and recirculation is deliberately induced on a regular basis, OR</li> <li>b. conventional Color-Flow Doppler at a minimum of once every three months.</li> </ul> </li> <li>Techniques and frequencies used to measure venous pressure include: <ul style="list-style-type: none"> <li>a. dynamic venous pressure measured at every hemodialysis session; uses low blood pump flow rates usually set at 200 mL/min., OR</li> <li>b. static venous pressure measured at a minimum of once every two weeks; performed at zero blood pump flow.</li> </ul> </li> </ul> </li> <li>• Indicate “<b>NO</b>” for this question if you only conduct (or note) the following clinical assessments: <ul style="list-style-type: none"> <li>a. Prolonged bleeding after needle withdrawal.</li> <li>b. Altered characteristics of thrill or bruit.</li> <li>c. Adequacy measurements using Kt/V or URR.</li> <li>d. Recirculation methods.</li> </ul> </li> </ul>
<p>Continue with question 2 if answered “yes” above and check all surveillance methods utilized based on the definitions and intervals given above. If other techniques and/or corresponding intervals were used check “other” and write in the technique and corresponding intervals.</p>
<p><b>Catheter or Port Access:</b> If the vascular access marked for question 21 was a catheter or port access, indicate in the appropriate space the <b>reason for the catheter or port access.</b></p>
<p>Continue with question 2 and indicate in the appropriate space <b>if one or more catheters or port accesses</b> had been used <b>continuously</b> in this patient for the past <b>90 days or longer</b> between OCT 1, 2003 and DEC 31, 2003.</p>
<p><b>Unknown:</b> If the vascular access in question 21 is unknown indicate by checking the “unknown” box and then continue to question 22.</p>
<p><b>22:</b> Check the appropriate space to indicate if the patient <b>FIRST</b> started hemodialysis during January 1, 2003-August 31, 2003 (see date #8 on page 1). These patients would have begun a regular maintenance course of hemodialysis during January 1, 2003-August 31, 2003. <b>DO NOT</b> include patients who have transferred from peritoneal dialysis, had a newly failed trans plant, or returned after an episode of regained kidney function, and were placed on maintenance hemodialysis during the time frame January 1, 2003-August 31, 2003. If “Yes”, answer questions 22A-B. If “No”, questions 22A-B should be left blank and the form has been completed.</p>
<p><b>22A:</b> Check the appropriate space to indicate type of vascular access in use upon <b>Initiation</b> of a maintenance course of hemodialysis (see date #8 on page 1) during the time frame January 1, 2003-August 31, 2003. Exclude patients who have received intermittent dialysis treatments for volume overload or congestive heart failure. (“Port Access” is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).</p>
<p><b>22B:</b> Check the appropriate space to indicate type of vascular access, for the patient identified in 22A, <b>in use 90 days after</b> the patient first started hemodialysis. (“Port Access” is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).</p>

## Appendix 3. 2003 CPM Data Collection Form – Peritoneal Dialysis

## PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

[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 LABEL IN THE SPACE BELOW
<div style="background-color: #cccccc; width: 80%; margin: 0 auto; padding: 10px;">           Place Patient Data Label Here         </div>	
<b>12. If this patient is unknown or was not dialyzed in the facility at any time during OCT 2003-MAR 2004 return the blank form to the Network.</b>	
13. Patient's Ethnicity (Check appropriate box). <input type="checkbox"/> non-Hispanic <input type="checkbox"/> Hispanic, Mexican American (Chicano) <input type="checkbox"/> Hispanic, Puerto Rican <input type="checkbox"/> Hispanic, Cuban American <input type="checkbox"/> Hispanic, Other _____ <input type="checkbox"/> Unknown	
14a. Patient's height (MUST COMPLETE): _____ inches OR _____ centimeters	
14b. Patient's weight (abdomen empty) (first clinic visit weight after Oct. 1, 2003): _____ . ____ lbs. OR _____ . ____ kg.	
15. Did patient have limb amputation(s) prior to Mar. 31, 2004: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
16. Has the patient ever been diagnosed with any type of diabetes? <input type="checkbox"/> Yes (go to 17) <input type="checkbox"/> No (go to 18) <input type="checkbox"/> Unknown (go to 18)	
17. If question 16 was answered YES, was the patient taking medications to control the diabetes during the study period? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If YES, was the patient using insulin during the study period? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
<b>Individual Completing Form (Please print):</b> First name: _____ Last name: _____ Title: _____ Phone number: (_____) _____ - _____ Fax number: (_____) _____ - _____	

### INSTRUCTIONS FOR COMPLETING THE PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004

The label on the top left side of this form contains the following patient identifying information (#'s 1-11). If the information is incorrect make corrections to the right of the label.

- |                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. LAST and first name.<br>3. SOCIAL Security Number (SSN).<br>5. GENDER (1=Male; 2=Female).<br>7. PRIMARY cause of renal failure by CMS-2728 code.<br>9. ESRD Network number.<br>Do not make corrections to this item. | 2. DATE of birth (DOB) as MM/DD/YYYY.<br>4. HEALTH Insurance Claim Number (HIC), ( <b>same as Medicare number</b> ).<br>6. RACE (1=American Indian/Alaska Native; 2=Asian; 3=Black; 4=White; 5=Unknown; 6=Pacific Islander; 7=Mid East Arabian; 8=Indian Subcontinent; 9=Other Multiracial).<br>8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.<br>10. Facility's Medicare provider number.<br>11. The most RECENT date this patient returned to peritoneal dialysis following: transplant failure, an episode of regained kidney function, or switched modality. |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
12. If the patient is unknown or if the patient was not dialyzed in the facility at any time during OCT 2003 through MAR 2004, send the blank form back to the ESRD Network office. Provide the name and address of the facility providing services to this patient on December 31, 2003, if known.
13. Patient's Ethnicity. Please verify the patient's ethnicity with the patient and check appropriate box.
- 14a. 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 15.
- 14b. Enter the patient's weight (abdomen empty) in pounds or kilograms. Use the FIRST CLINIC VISIT weight on or after October 1, 2003.
15. 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 prior to Mar. 31, 2004.**
16. Check either "Yes", "No", or "Unknown" to indicate if the patient has ever been diagnosed with any type of diabetes. If YES, proceed to question 17.
17. Check either "Yes", "No", or "Unknown" to indicate if the patient was taking medications to control the diabetes during the study period. If the answer to 17 is YES, please check either "Yes", "No", or "Unknown" to indicate if the patient was using insulin during the study period. Study period is OCT 2003 -MAR 2004.

PLEASE COMPLETE ITEMS 18 THROUGH 24 ON PAGE 2, 3, AND 4 OF THIS DATA COLLECTION FORM.  
INSTRUCTIONS FOR COMPLETING THESE ITEMS ARE ON PAGES 5 AND 6.

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)			
<b>18. ANEMIA MANAGEMENT: For each lab question below, enter the first lab value obtained for each two-month time period: OCT-NOV 2003, DEC 2003-JAN 2004, FEB-MAR 2004. Enter NF/NP if the lab value cannot be located.</b>			
	OCT-NOV 2003	DEC 2003-JAN 2004	FEB-MAR 2004
A. First laboratory hemoglobin (Hgb) during _____ the two-month time period:	. _____ g/dL _____ (If NF/NP go to 18C)	. _____ g/dL _____ (If NF/NP go to 18C)	. _____ g/dL _____ (If NF/NP go to 18C)
B.1.a. Did the patient receive Epoetin at anytime during the 30 days before the Hgb in 18A was drawn?	Epoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
B.1.b. Did the patient receive Darbepoetin (Aranesp™) at anytime during the 30 days before the Hgb in 18A was drawn?	Darbepoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
B.2.a. What was the PRESCRIBED Epoetin dose in units/month at the time immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 5)	Epoetin: _____ units/month	Epoetin: _____ units/month	Epoetin: _____ units/month
B.2.b. What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A was drawn? (See instructions on page 5)	Darbepoetin: _____ mcg/month	Darbepoetin: _____ mcg/month	Darbepoetin: _____ mcg/month
B.3.a. How many times per month was Epoetin prescribed?	Epoetin: _____ x per month	Epoetin: _____ x per month	Epoetin: _____ x per month
B.3.b. How many times per month was Darbepoetin prescribed?	Darbepoetin: _____ x per month	Darbepoetin: _____ x per month	Darbepoetin: _____ x per month
B.4.a. What was the prescribed route of administration for Epoetin? (Check all that apply)	Epoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Epoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown
B.4.b. What was the prescribed route of administration for Darbepoetin? (Check all that apply)	Darbepoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown	Darbepoetin: <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> Unknown
C. First serum ferritin concentration during the two-month time period:	_____ ng/mL	_____ ng/mL	_____ ng/mL
D. First % transferrin (iron) saturation during the two-month time period:	_____ %	_____ %	_____ %
E. Was iron prescribed at any time during the two-month time period?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19) <input type="checkbox"/> Unknown (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19) <input type="checkbox"/> Unknown (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19) <input type="checkbox"/> Unknown (go to 19)
F. If yes, what was the prescribed route of iron administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> PO <input type="checkbox"/> Unknown	<input type="checkbox"/> IV <input type="checkbox"/> PO <input type="checkbox"/> Unknown	<input type="checkbox"/> IV <input type="checkbox"/> PO <input type="checkbox"/> Unknown
G. If the patient was prescribed IV iron, what was the total dose of IV iron administered during the two-month time period?	_____ mg	_____ mg	_____ mg
<b>19. SERUM ALBUMIN: Enter the first serum albumin obtained for each two-month time period: OCT-NOV 2003, DEC 2003-JAN 2004, FEB-MAR 2004. Enter NF/NP if the lab value cannot be located. Check the method used (BCG/bromocresol green or BCP/bromocresol purple) by the lab to determine serum albumin. If lab method unknown, call lab to find out.</b>			
	OCT-NOV 2003	DEC 2003-JAN 2004	FEB-MAR 2004
A. First serum albumin during the two-month time period:	_____ . _____ g/dL	_____ . _____ g/dL	_____ . _____ g/dL
B. Check lab method used: BCG = bromocresol green; BCP = bromocresol purple	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP
<b>20. PERITONEAL DIALYSIS ADEQUACY: The remainder of this form lists a series of questions regarding adequacy measurements for this patient. Please answer questions 20A and B FOR EACH TWO-MONTH TIME PERIOD indicated. Then continue to pages 3 and 4.</b>			
	OCT-NOV 2003	DEC 2003-JAN 2004	FEB-MAR 2004
A. Was the patient on peritoneal dialysis at any time during this period?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
B. Was the patient on hemodialysis or did patient receive a transplant at any time during this period?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10. Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)			
<p><b>21. ADEQUACY:</b> The following data are requested for the <b>FIRST ADEQUACY</b> determination during the months <b>OCTOBER 2003</b> through <b>MARCH 2004</b>. Starting with the first adequacy measurement in these months, enter the adequacy measurements/results listed below that were obtained. (Please <b>DO NOT</b> record more than one adequacy measurement done for any one month.) Please read instructions on Pages 5 and 6 before completing this section. Enter <b>NF/NP</b> if information cannot be located.</p>		<p><b>22. PERITONEAL DIALYSIS PRESCRIPTION:</b> For the following questions – record the PD prescription in effect at the time the adequacy measures/results recorded in Question 21 were performed. Please read instructions on Page 6 before completing this section. Enter <b>NF/NP</b> if information cannot be located.</p>	
21.	Was adequacy measurement done during OCT 2003-MAR 2004?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Prescription at the time adequacy was measured in 21A
21A.	Date of <b>FIRST</b> adequacy measurement between 10-1-2003 to 3-31-2004	___ / ___ / ___ (mm) (dd) (yyyy)	<p><b>22A. CAPD PRESCRIPTION</b> (this includes patients with one overnight exchange using an assist device)</p> 1. Number of dialysis days per week _____ (# days) 2. Total dialysate volume infused per 24 hours _____ mL/24 hrs 3. Total number of exchanges per 24 hours (including overnight exchange) _____ (# exchanges)
21B.	Patient's dialysis modality when adequacy measures were performed	<input type="checkbox"/> CAPD <input type="checkbox"/> Cycler (See definitions in instructions on p. 5)	
21C.	Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs)	_____ . ___ lbs /kgs	<p><b>22B. CYCLER PRESCRIPTION</b></p> 1. Number of dialysis days per week _____ (# days) 2. Total dialysate volume infused per 24 hours _____ mL/24 hrs 3. Total dialysis time a. Total nighttime dialysis time _____ hrs _____ min b. Total daytime dialysis time _____ hrs _____ min c. Total amount of time the patient is dry during 24 hours _____ hrs _____ min ( <b>Note:</b> 3a+b+c = 24 hours) 4. Nighttime Prescription (excluding last bag fill) a. Volume of a single nighttime exchange _____ mL/exchange b. Number of dialysis exchanges during the nighttime _____ (#/nighttime) 5. Daytime Prescription (including last bag fill) a. Volume of a single daytime exchange _____ mL/exchange b. Number of dialysis exchanges during the daytime _____ (#/daytime)
21D.	Weekly Kt/V <sub>urea</sub> (dialysate and urine clearance)	_____ . _____	
21E.	Method by which V above was calculated: Check one. (If unknown please call lab.)	<input type="checkbox"/> %BW <input type="checkbox"/> Hume <input type="checkbox"/> Watson <input type="checkbox"/> Other _____	
21F.	Weekly Creatinine Clearance (dialysate and urine clearance)	_____ . ___ L/wk	<p>6. Does the cycler prescription described above include TIDAL dialysis?  <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p>
21G.	Is this Creatinine Clearance corrected for body surface area, using standard methods? (See instructions on page 6)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
21H.	24 hr DIALYSATE volume (prescribed and ultrafiltration)	_____ mL	<p><b>22C. Based on the adequacy result from questions 21A-O,</b></p> 1. Was the collection repeated? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown 2. Was the prescription changed? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
21I.	24 hr DIALYSATE urea nitrogen:	_____ . ___ mg/dL	
21J.	24 hr DIALYSATE creatinine:	_____ . ___ mg/dL	
21K.	24 hr URINE volume: (If 24 hr urine was not located check NF/NP.)	_____ mL <input type="checkbox"/> NF/NP	
21L.	24 hr URINE urea nitrogen:	_____ . ___ mg/dL	
21M.	24 hr URINE creatinine:	_____ . ___ mg/dL	
21N.	SERUM BUN at the time this adequacy assessment was done	_____ mg/dL	
21O.	SERUM creatinine at the time this adequacy assessment was done	_____ . ___ mg/dL	
21P.1.	Most recent 4 hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET).	_____ . _____	
21P.2.	Date of most recent D/P Cr	___ / ___ / ___ (mm) (dd) (yyyy)	

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FOR 2004: (CONTINUED)			
<p><b>23. ADEQUACY:</b> The following data are requested for the <b>SECOND ADEQUACY</b> determination during the months <b>NOVEMBER 2003 through MARCH 2004</b>. Starting with the second adequacy measurement in these months, enter the adequacy measurements/results listed below that were obtained. (Please <b>DO NOT</b> record more than one adequacy measurement done for any one month.) Please read instructions on Page 6 before completing this section. Enter NF/NP if information cannot be located.</p>		<p><b>24. PERITONEAL DIALYSIS PRESCRIPTION:</b> For the following questions – record the PD prescription in effect at the time the adequacy measures/results recorded in Question 23 were performed. Please read instructions on Page 6 before completing this section. Enter NF/NP if information cannot be located.</p>	
23.	Was second adequacy measurement done during NOV 2003-MAR 2004?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Prescription at the time adequacy was measured in 23A
23A.	Date of <b>SECOND</b> adequacy measurement between 11-1-2003 to 3-31-2004	___ / ___ / ___ (mm) (dd) (yyyy)	<p><b>24A. CAPD PRESCRIPTION</b> (this includes patients with one overnight exchange using an assist device)</p> 1. Number of dialysis days per week _____ (# days)
23B.	Patient's dialysis modality when adequacy measures were performed	<input type="checkbox"/> CAPD <input type="checkbox"/> Cycler (See definitions in instructions on p. 5)	
23C.	Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs)	_____ lbs /kgs	2. Total dialysate volume infused per 24 hours _____ mL/24 hrs
23D.	Weekly Kt/V <sub>urea</sub> (dialysate and urine clearance)	_____ . _____	3. Total number of exchanges per 24 hours (including overnight exchange) _____ (# exchanges)
23E.	Method by which V above was calculated: Check one. (If unknown please call lab)	<input type="checkbox"/> %BW <input type="checkbox"/> Hume <input type="checkbox"/> Watson <input type="checkbox"/> Other _____	<p><b>24B. CYCLER PRESCRIPTION</b></p> 1. Number of dialysis days per week _____ (# days)
23F.	Weekly Creatinine Clearance (dialysate and urine clearance)	_____ . _____ L/wk	
23G.	Is this Creatinine Clearance corrected for body surface area, using standard methods? (See instructions on page 6)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	2. Total dialysate volume infused per 24 hours _____ mL/24 hrs
23H.	24 hr DIALYSATE volume (prescribed and ultrafiltration)	_____ mL	3. Total dialysis time a. Total nighttime dialysis time _____ hrs   _____ min b. Total daytime dialysis time _____ hrs   _____ min c. Total amount of time the patient is dry during 24 hours _____ hrs   _____ min (Note: 3a+b+c = 24 hours)
23I.	24 hr DIALYSATE urea nitrogen:	_____ . _____ mg/dL	4. Nighttime Prescription (excluding last bag fill) a. Volume of a single nighttime exchange _____ mL/exchange b. Number of dialysis exchanges during the nighttime _____ (#/nighttime)
23J.	24 hr DIALYSATE creatinine:	_____ . _____ mg/dL	5. Daytime Prescription (including last bag fill) a. Volume of a single daytime exchange _____ mL/exchange b. Number of dialysis exchanges during the daytime _____ (#/daytime)
23K.	24 hr URINE volume: (If 24 hr urine was not located check NF/NP.)	_____ mL <input type="checkbox"/> NF/NP	
23L.	24 hr URINE urea nitrogen:	_____ . _____ mg/dL	6. Does the prescription described above include TIDAL dialysis? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
23M.	24 hr URINE creatinine:	_____ . _____ mg/dL	
23N.	SERUM BUN at the time this adequacy assessment was done	_____ mg/dL	<p><b>24C. Based on the adequacy result from questions 23A-O,</b></p> 1. Was the collection repeated? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown 2. Was the prescription changed? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
23O.	SERUM creatinine at the time this adequacy assessment was done	_____ . _____ mg/dL	
23P.	If the patient has had a 4-Hour D/P Cr performed from a PET since the time of the first adequacy test, enter the value and the date the test was performed. If not performed, enter NP.	_____ . _____ _____ / _____ / _____ (mm) (dd) (yyyy)	

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)	
<b>INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 20 (continued from page 1): To answer questions 18 through 20 review the patient's clinic or facility medical record FOR EACH TWO-MONTH TIME PERIOD: OCT 1, 2003 through NOV 30, 2003, DEC 1, 2003 through JAN 31, 2004, and FEB 1, 2004 through MAR 31, 2004. Do not leave any items blank. Enter NF/NP if the following information cannot be located.</b>	
<b>18A:</b>	Enter the patient's FIRST hemoglobin (Hgb) value determined by the laboratory for EACH two-month time period. If not found or not performed during the two-month time period, enter NF/NP.
<b>18B.1:</b>	Check the appropriate box to indicate if the patient received EPOETIN or DARBEPOETIN (Aranesp™) at anytime during the 30 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to question 18C.
<b>18B.2:</b>	If <b>Epoetin</b> was prescribed, enter the PRESCRIBED MONTHLY Epoetin dose, <b>not the administered dose</b> , in units given at the time immediately before the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a dose, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 unit prescribed dose.)  If <b>Darbepoetin</b> (Aranesp™) was prescribed, enter the PRESCRIBED MONTHLY Darbepoetin dose, <b>not the administered dose</b> , in micrograms per month during the month immediately before the date of the hemoglobin value in 18A, even if the patient did not receive the dose. This includes any prescribed dose not given because of an error or the patient missed a dose, etc. Enter "0" if the patient was on "Hold". (For the purposes of this collection, a "Hold" order will be considered a 0 mcg/month prescribed dose.)
<b>18B.3:</b>	Enter the number of times per month that Epoetin was prescribed OR the number of times per month Darbepoetin was prescribed.
<b>18B4:</b>	Check the appropriate box to indicate the prescribed route of administration for Epoetin or for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient received Epoetin or Darbepoetin IV and SC during the month, please check both boxes.
<b>18C:</b>	Enter the patient's FIRST serum ferritin concentration recorded EACH two-month time period. If a serum ferritin concentration test was not found or not performed every two-month time period, enter the value for the time period when performed and record NF/NP for the other time period(s).
<b>18D:</b>	Enter the patient's FIRST % transferrin (iron) saturation recorded EACH two-month time period. If a % transferrin (iron) saturation test was not found or not performed every two-month time period, enter the value for the time period when performed and record NF/NP for the other time period(s).
<b>18E:</b>	Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the two-month time periods.
<b>18F:</b>	If the answer to 18E is "Yes", please check the appropriate space to indicate the route of iron administration (intravenous [IV] or by mouth [PO]) for each two-month time period. Check every route of administration that was prescribed each time period.
<b>18G:</b>	If the patient was prescribed IV iron, add together all doses that were given during each two-month time period OCT-NOV 2003, DEC 2003-JAN 2004, FEB-MAR 2004 and enter the TOTAL dose of IV iron (in mg) <b>administered</b> .
<b>19A:</b>	Enter the patient's FIRST serum albumin value recorded EACH two-month time period.
<b>19B:</b>	Check the 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.
<b>20A:</b>	Check the appropriate response (yes or no) for each two-month time period, indicating whether this patient was on peritoneal dialysis at any time during each of the specified two-month time periods.
<b>20B:</b>	Check the appropriate response (yes or no) for each two-month time period, indicating whether this patient was on hemodialysis or received a transplant at any time during each of the specified two-month time periods.
<b>INSTRUCTIONS FOR COMPLETING QUESTIONS 21 THROUGH 24: To answer questions 21 through 24 review the patient's clinic or facility medical record and provide the requested data for each of the first two adequacy measurements and PD prescriptions in effect at the time the adequacy measurements were done during the months OCTOBER 2003 through MARCH 2004. DO NOT record more than one adequacy measurement done for any one month.</b>	
<b>21.</b>	Check "yes", "no", or "unknown" to indicate if an adequacy measurement was done between OCT 1, 2003 through MAR 31, 2004.
<b>21A:</b>	Enter the first date on which adequacy of dialysis was assessed for the first measure obtained between OCT 1, 2003 through MAR 31, 2004. DO NOT record more than one adequacy measurement done for any one month.
<b>21B:</b>	Check the modality of peritoneal dialysis this patient was on at the time the corresponding adequacy of dialysis measure was obtained. CHECK either CAPD or Cycler. CAPD includes patients with one overnight exchange using an assist device. Cycler includes patients using an automated device for exchanges.
<b>21C:</b>	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.
<b>21D:</b>	Enter the TOTAL WEEKLY Kt/V <sub>urea</sub> for the first adequacy measurement indicated on 21A between OCT 1, 2003 through MAR 31, 2004. NOTE: Whether or not you have a value for weekly Kt/V <sub>urea</sub> for this adequacy assessment, please complete the corresponding values for questions 21H-21I for 24-hour dialysate volume, 24-hour dialysate urea and question 21K for 24-hour urine volume. If the patient is not anuric, complete the corresponding value for question 21L, the 24-hour urine urea, if this value is available. Enter NF/NP for all values when not found or not performed. If your unit calculates a daily Kt/V <sub>urea</sub> , 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 <sub>urea</sub> by the number of days the patient did dialyze.

<b>PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2004 (CONTINUED)</b>	
<b>21E:</b>	Check the method used to calculate the V in the $Kt/V_{\text{urea}}$ 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.
<b>21F:</b>	Enter the TOTAL WEEKLY CREATININE CLEARANCE for the first adequacy measurement indicated on 21A between OCT 1, 2003 through MAR 31, 2004. NOTE: Whether or not you have a value for weekly creatinine clearance for this adequacy assessment, please complete the corresponding values for questions 21H and 21J for 24-hour dialysate volume, 24-hour dialysate creatinine and question 21K for 24-hour urine volume. If the patient is not anuric, complete the corresponding value for question 21M, the 24-hour urine creatinine, if this value is available. Enter NF/NP for all values when not found or not performed. If your unit calculates a 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 creatinine clearance by the number of days the patient did dialyze.
<b>21G:</b>	Check Yes or No if the weekly creatinine clearance was normalized for body surface area (i.e., the result is multiplied by 1.73m <sup>2</sup> and divided by the patient's body surface area [BSA]). 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 creatinine clearance value for this information. Please do not leave blank.
<b>21H, I, and J:</b>	Enter the measured 24-hour DIALYSATE volume (includes prescribed and ultrafiltration volumes), urea nitrogen and creatinine obtained for the first adequacy measurement obtained between OCT 1, 2003 through MAR 31, 2004. If a 24-hour dialysate volume, urea nitrogen or creatinine were NOT measured in this time period, enter NF/NP (for not found or not performed) in the appropriate spaces. ONLY ENTER ACTUAL MEASURED 24-HOUR DIALYSATE VOLUME. DO NOT ENTER AN EXTRAPOLATED DIALYSATE VOLUME. Please report the 24-hour dialysate volume as a combination of the prescribed fill volume and the ultrafiltration volume.
<b>21K, L, and M:</b>	Enter the 24-hour URINE volume, urea nitrogen and creatinine obtained for the first adequacy assessment obtained between OCT 1, 2003 through MAR 31, 2004. ONLY ENTER ACTUAL MEASURED 24-HOUR URINE VOLUME—DO NOT ENTER AN EXTRAPOLATED URINE VOLUME. If 24-hour urine volume was not collected check NF/NP for not found or not performed. If NF/NP is checked, SKIP TO QUESTION 21N. If urine urea nitrogen and creatinine were not found or not measured in this time period, enter NF/NP in the appropriate spaces.
<b>21N, O:</b>	Enter the SERUM BUN and SERUM CREATININE obtained for the first adequacy assessment obtained between OCT 1, 2003 through MAR 31, 2004. Enter NF/NP in the appropriate spaces for all time periods when not found or not performed.
<b>21P:</b>	(1) Enter the most recent four hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET). (2) Enter the date of the most recent D/P Cr. The test result and corresponding date of the most recent D/P Cr may be outside the 6-month study period. If never found or performed record NF/NP. Date cannot be after 3/31/04 or prior to the first day of peritoneal dialysis.
<b>22:</b>	To respond to questions 22A through 22C record the peritoneal dialysis (PD) prescription in effect at the time of the first adequacy measures/results recorded in question 21 performed between OCT 1, 2003 through MAR 31, 2004. Complete all items that are applicable.
<b>22A:</b>	CAPD PRESCRIPTION. Use the CAPD prescription category for all CAPD patients including patients with one overnight exchange using an assist device. (1) Enter the number of days per week for which this patient underwent peritoneal dialysis. (2) Enter the total dialysate volume in mL infused over a 24-hour period and (3) the number of exchanges per 24-hour period PRESCRIBED for CAPD at the time the first adequacy measurements were performed.
<b>22B:</b>	CYCLER PRESCRIPTION. (1) Enter the number of days per week for which this patient underwent peritoneal dialysis. (2) Enter the total dialysate volume in mL infused over a 24-hour period. (3) Total dialysis time - (Note: 2a+b+c = 24 hours): (3a) Enter the total nighttime dialysis time, (3b) the total daytime dialysis dwell time, and (3c) the total amount of time the patient is dry during 24 hours. If the patient is never dry in 24 hours enter a value of 0 hours. The hours entered in 2a, b, & c should equal 24 hours. (4) Nighttime Prescription (excluding last bag fill): (4a) Enter the volume of a single nighttime exchange and (4b) the number of dialysis exchanges during the nighttime PRESCRIBED for CYCLER NIGHTTIME at the time the first adequacy measurements were performed. Include in the CYCLER NIGHTTIME prescription only those exchanges provided by an automated device. DO NOT include in this category any last bag fill or option that the patient carries after unhooking from the cyclor or any daytime dwells as these exchanges are recorded in the DAYTIME PRESCRIPTION information. If different inflow volumes are used, report average inflow volume. (5) Daytime Prescription (including last bag fill): (5a) Enter the volume of a single daytime exchange and (5b) the number of dialysis exchanges during the daytime PRESCRIBED for CYCLER DAYTIME at the time the first adequacy measurements were performed. Include in the CYCLER DAYTIME prescription only those exchanges performed after the patient disconnects from the cyclor and/or a last bag fill or option that the patient carries during the day. ANY OTHER EXCHANGES PERFORMED USING THE CYCLER SHOULD BE INCLUDED UNDER CYCLER NIGHTTIME PRESCRIPTION. If different inflow volumes are used, report average inflow volume.
	(6) Check the appropriate box, "yes" or "no", indicating whether this patient's peritoneal dialysis prescription included TIDAL dialysis. TIDAL patients are cyclor patients for whom the dialysate is partially drained between some exchanges.
<b>22C:</b>	(1) Check the appropriate box, "yes" or "no", indicating whether the adequacy collection was repeated, and (2) check the appropriate box "yes" or "no", indicating whether the prescription changed following the first adequacy measurement performed between OCT 1, 2003 through MAR 31, 2004.
<b>23:</b>	Check "yes", "no", or "unknown" to indicate if an adequacy measurement was done between NOV 1, 2003 through MAR 31, 2004.
<b>23A-O:</b>	See instructions for 21A-21O and complete for second adequacy measurement performed between NOV 1, 2003 through MAR 31, 2004. DO NOT record more than one adequacy measurement done for any one month.
<b>23P:</b>	Record the value and date of the patient's PET if a new one was performed since the time of the first adequacy test. If not performed enter NP.
<b>24A-C:</b>	See instructions for 22A-22C and complete for the peritoneal dialysis (PD) prescription in effect at the time of the second adequacy measures/results recorded in question 23 performed between NOV 1, 2003 through MAR 31, 2004.

## Appendix 4. Centers for Medicare & Medicaid Services (CMS) Offices and ESRD Networks

### CMS Offices

Centers for Medicare & Medicaid Services  
Office of Clinical Standards & Quality  
Quality Measurement and Health Assessment  
Group  
Mailstop S3-02-01  
7500 Security Boulevard  
Baltimore, MD 21244  
(410) 786-5785

Centers for Medicare & Medicaid Services -  
Region I  
Division of Clinical Standards and Quality,  
Clinical Standards Branch  
Room 2275  
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Centers for Medicare & Medicaid Services -  
Region VI  
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Centers for Medicare & Medicaid Services -  
Region VII  
Division of Clinical Standards and Quality,  
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Seattle, WA 98121-2500  
(206) 615-2317

### ESRD Networks

ESRD Network Organization No. 1  
ESRD Network of New England, Inc.  
30 Hazel Terrace  
Woodbridge, CT 06525  
Region I: ME, NH, VT, MA, CT, RI  
(203) 387-9332

ESRD Network Organization No. 2  
ESRD Network of New York, Inc.  
1249 Fifth Avenue A-419  
New York, NY 10029  
Region I: NY  
(212) 289-4524

ESRD Network Organization No. 3  
TransAtlantic Renal Council  
Cranbury Gates Office Park  
109 South Main Street, Suite 21  
Cranbury, NJ 08512-9595  
Region I: NJ, PR, VI  
(609) 490-0310

ESRD Network Organization No. 4  
40 24<sup>th</sup> Street, Suite 410  
Pittsburgh, PA 15222  
Region: DE, PA  
(412) 325-2250

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  
Southeastern Kidney Council, Inc.  
1000 St. Albans Drive  
Suite 270  
Raleigh, NC 27609  
Region VI: GA, NC, SC  
(919) 855-0882

ESRD Network Organization No. 7  
FMQAI: The Florida ESRD Network  
4350 West Cypress Street, Suite 900  
Tampa, FL 33607  
Region: FL  
(813) 383-1530

ESRD Network Organization No. 8  
Network Eight, Inc.  
P.O. Box 55868  
Jackson, MS 39296-5868  
Region VI: AL, MS, TN  
(601) 936-9260

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

ESRD Network Organization No. 11  
Renal Network of the Upper Midwest, Inc.  
1360 Energy Park Drive, Suite 200  
St. Paul, MN 55108  
Region: MI, MN, ND, SD, WI  
(651) 644-9877

ESRD Network Organization No. 12  
7505 NW Tiffany Springs Parkway, Suite 230  
Kansas City, MO 64153  
Region VII: MO, IA, NE, KS  
(816) 880-9990

ESRD Network Organization No. 13  
4200 Perimeter Center Drive, Suite 102  
Oklahoma City, OK 73112-2314  
Region: AR, LA, OK  
(405) 942-6000

ESRD Network Organization No. 14  
ESRD Network of Texas, Inc.  
14114 Dallas Parkway, # 660  
Dallas, TX 75240-4349  
Region VI: TX  
(972) 503-3215

ESRD Network Organization No. 15  
Intermountain ESRD Network, Inc.  
1301 Pennsylvania Street, Suite 750  
Denver, CO 80203-5012  
Region X: NM, CO, WY, UT, AZ, NV  
(303) 831-8818

ESRD Network Organization No. 16  
Northwest Renal Network  
4702 42nd Avenue, SW  
Seattle, WA 98116  
Region X: MT, AK, ID, OR, WA  
(206) 923-0714

ESRD Network Organization No. 17  
TransPacific Renal Network  
4470 Redwood Highway, Suite 102  
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,  
Inc.  
6255 Sunset Boulevard, Suite 2211  
Los Angeles, CA 90028  
Region X: So. CA  
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## Appendix 5. ESRD CPM Quality Improvement Committee Members

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\* Vascular Access Subcommittee Member

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## Appendix 6. List of Publications/Abstracts/Supplemental Reports of ESRD CPM and Core Indicators Data

### Adult Publications

1. McClellan WM, Frederick P, Helgerson S, Hayes R, Ballard D, McMullan M. A Health Care Quality Improvement Program for End-Stage Renal Disease (ESRD). *Health Care Financing Review* 1995; 16:129-140.
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3. Neu AM, Bedinger MR, Fivush BA, Warady BA, Watkins SL, Friedman AL, Brem AS, Goldstein SL, Frankenfield DL. Growth in adolescent hemodialysis patients: Data from the Centers for Medicare & Medicaid Services ESRD Clinical Performance Measures Project. *Pediatric Nephrology* [in press].
4. Gorman G, Fivush B, Frankenfield D, Warady B, Watkins S, Brem A, Neu A. Short stature and growth hormone use in pediatric hemodialysis patients. *Pediatric Nephrology* [in press].

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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.
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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.
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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.
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**Adult Abstracts (continued)**

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## Supplemental Reports

### 1994

#### *Supplemental Report #1*

Results of validation study: comparison of data abstracted by ESRD facility staff and by ESRD Network staff (April 1995)

#### *Supplemental Report #2*

Questions and answers regarding core indicator results for a variety of facility and patient characteristics (May 1995)

#### *Supplemental Report #3*

The mortality and morbidity experience from January through June 1994 for patients described by core indicators values in October through December, 1993 (October 1995)

#### *Special Populations Report*

Results for American Indians and Alaska Natives identified in the 1994 ESRD Core Indicators Project (April 1995)

### 1995

#### *Supplemental Report # 1*

\*Association of body weight with adequacy of dialysis (August 1996)

#### *Special Populations Report*

Results for American Indians and Alaska Natives receiving in-center hemodialysis in ESRD Networks 11, 15, and 16 (September 1996)

### 1996

#### *Special Report #A*

Results of 1996 validation study: Analysis of concurrence between Core Indicators data abstracted by dialysis facility staff and ESRD Network staff (April 1997)

#### *Special Report #B*

Influenza immunization of ESRD patients October, November, and December 1995 (July 1997)

#### *Supplemental Report #1*

Predictors for a delivered hemodialysis treatment of < 0.65 URR (March 1997)

#### *Supplemental Report #2*

Sub-optimal serum albumin levels of adult, in-center hemodialysis patients: Results from the 1996 ESRD Core Indicators Project (May 1997)

#### *Supplemental Report #3*

Description of a cohort's experience: ESRD Core Indicators Project, 1993-1995 (June 1997)

#### *Supplemental Report #4*

Gender analysis of the 1996 ESRD Core Indicators data (December 1997)

### 1997

#### *Special Report #A*

Results of 1997 validation study: Analysis of concurrence between Core Indicators data abstracted by dialysis facility staff and ESRD Network staff (May 1998)

#### *Supplemental Report #1*

\*Analysis of Core Indicators results by race/ethnicity for adult (aged  $\geq 18$  years) in-center hemodialysis and peritoneal dialysis patients (February 1998)

#### *Supplemental Report #2*

\*Adequacy measures for adult peritoneal dialysis patients (March 1998)

#### *Supplemental Report #3*

\*The management of anemia in adult in-center hemodialysis and peritoneal dialysis patients (April 1998)

### 1998

#### *Special Report #A*

Results of 1998 validation study: Analysis of concurrence between Core Indicators data abstracted by dialysis facility staff and ESRD Network staff (February 1999)

#### *Supplemental Report #1*

\*Comparison of demographic and selected intermediate outcome measures for health maintenance organization (HMO) and fee-for-service (FFS) adult in-center hemodialysis patients (February 1999)

#### *Supplemental Report #2*

\*Comparison of selected intermediate clinical measures by years on dialysis (April 1999)

### 1999

#### *Supplemental Report #1*

\*Vascular access for in-center hemodialysis patients: Preliminary findings (February 2000)

#### *Supplemental Report #2*

Network trends, 1993-1999 (July 2000)

## Supplemental Reports (continued)

### 2000

#### *Supplemental Report #1*

\*A study of pediatric ( $\geq 12$  and  $< 18$  years old) in-center hemodialysis patients: Results from the 2000 End Stage Renal Disease (ESRD) Clinical Performance Measures Project (January 2001)

#### *Supplemental Report #2*

\*Hemodialysis CPMs IV and V: Results from the pilot-test of the facility questionnaire, 1999-2000 (March 2001)

#### *Supplemental Report #3*

\*Comparison of facility-reported, calculated, and prescribed dialysis adequacy values: Results from the 2000 End-Stage Renal Disease (ESRD) Clinical Performance Measures (CPM) Project (June 2001)

### 2001

#### *Supplemental Report #1*

\*Intermediate outcomes for adult Asian in-center hemodialysis patients in the U.S.: Results from the 2001 End Stage Renal Disease (ESRD) Clinical Performance Measures Project (December 2001)

#### *Supplemental Report #2*

\*Longitudinal analysis of pediatric ( $\geq 12$  and  $< 18$  years old) in-center hemodialysis patients: Results from the 2001 End-Stage Renal Disease (ESRD) Clinical Performance Measures Project (February 2002)

#### *Supplemental Report #4*

\*Intermediate outcomes for adult in-center hemodialysis patients in the U.S. by cause of ESRD: Results from the 2001 End-Stage Renal Disease (ESRD) Clinical Performance Measures Project (March 2002)

#### *Supplemental Report #5*

Intermediate outcomes for adult peritoneal dialysis patients in the U.S. by cause of ESRD: Results from the 2001 End-Stage Renal Disease (ESRD) Clinical Performance Measures Project (March 2002)

\* Supplemental Report either has been published or is being developed into a manuscript to be published in either a peer-reviewed journal or in a smaller journal

### 2002

#### *Supplemental Report #1*

\*Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) supplemental questionnaire: Impact of specialization of primary nephrologist on care of pediatric hemodialysis patients. (February 2003)

#### *Supplemental Report #2*

\*Analysis of intermediate outcomes for adult Hispanic in-center hemodialysis patients: Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) Project. (March 2003)

#### *Supplemental Report #3*

\*Analysis of intermediate outcomes for adult in-center hemodialysis patients with diabetes: Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) Project (May 2003)

#### *Supplemental Report #4*

Analysis of intermediate outcomes for adult peritoneal dialysis patients with diabetes: Results from the 2002 end-stage renal disease (ESRD) Clinical Performance Measures (CPM) Project (May 2003)

**APPENDIX 7 2004 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES  
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
<b># in sample</b>	475	485	488	479	482	487	476	482	490	461	475	442	488	487	482	478	482	495	<b>8634</b>
<b>Dialysis Adequacy</b>	<b>Net 1</b>	<b>Net 2</b>	<b>Net 3</b>	<b>Net 4</b>	<b>Net 5</b>	<b>Net 6</b>	<b>Net 7</b>	<b>Net 8</b>	<b>Net 9</b>	<b>Net 10</b>	<b>Net 11</b>	<b>Net 12</b>	<b>Net 13</b>	<b>Net 14</b>	<b>Net 15</b>	<b>Net 16</b>	<b>Net 17</b>	<b>Net 18</b>	<b>US</b>
% Pts with Mean spKt/V ≥ 1.2	93	88	91	93	90	93	90	89	91	90	88	90	88	96	91	92	87	91	<b>91</b>
Median spKt/V	1.53	1.52	1.50	1.54	1.50	1.53	1.51	1.51	1.54	1.55	1.48	1.54	1.49	1.62	1.58	1.59	1.49	1.54	<b>1.53</b>
% Pts with Mean URR ≥ 65%	90	83	86	89	85	87	87	86	88	88	83	85	84	91	89	89	84	87	<b>87</b>
Median URR %	72.9	72.2	72.4	72.9	72.2	72.4	72.0	72.1	72.7	73.2	71.2	72.8	71.4	74.2	73.9	73.8	71.8	72.7	<b>72.6</b>
Median Blood Pump Flow (mL/min)	394	400	400	400	400	400	400	403	400	403	400	400	400	400	400	393	400	400	<b>400</b>
<b>Vascular Access</b>	<b>Net 1</b>	<b>Net 2</b>	<b>Net 3</b>	<b>Net 4</b>	<b>Net 5</b>	<b>Net 6</b>	<b>Net 7</b>	<b>Net 8</b>	<b>Net 9</b>	<b>Net 10</b>	<b>Net 11</b>	<b>Net 12</b>	<b>Net 13</b>	<b>Net 14</b>	<b>Net 15</b>	<b>Net 16</b>	<b>Net 17</b>	<b>Net 18</b>	<b>US</b>
% Prevalent Pts with AVF	48	43	35	37	28	29	35	28	31	37	36	35	31	29	45	56	41	38	<b>35</b>
% Incident Pts with AVF	49	37	38	22	23	32	36	27	33	27	27	31	29	33	39	61	45	41	<b>35</b>
% Prevalent Pts with AVG	24	29	28	35	44	45	33	48	32	34	37	37	41	52	29	25	38	39	<b>38</b>
% pts with AVG and stenosis monitoring	79	66	73	89	69	73	75	73	72	77	77	76	84	91	62	85	80	82	<b>77</b>
% Prevalent Pts with catheter	28	28	37	28	28	26	31	24	36	29	27	28	28	19	26	20	21	22	<b>27</b>
% Prevalent Pts with catheter ≥ 90 days	18	22	29	21	22	18	21	18	26	19	19	22	19	15	21	13	16	15	<b>20</b>

**2004 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES (cont.)**  
**for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

<b>Anemia Mgmt.</b>	<b>Net 1</b>	<b>Net 2</b>	<b>Net 3</b>	<b>Net 4</b>	<b>Net 5</b>	<b>Net 6</b>	<b>Net 7</b>	<b>Net 8</b>	<b>Net 9</b>	<b>Net 10</b>	<b>Net 11</b>	<b>Net 12</b>	<b>Net 13</b>	<b>Net 14</b>	<b>Net 15</b>	<b>Net 16</b>	<b>Net 17</b>	<b>Net 18</b>	<b>US</b>
Median Hgb (g/dL)	11.9	12.0	11.8	11.9	11.9	11.9	11.8	11.8	12.0	12.0	12.1	11.7	11.8	11.8	12.0	11.8	11.9	11.9	<b>11.9</b>
% Pts with Mean Hgb ≥ 11g/dL	81	81	82	80	79	78	77	80	80	83	81	80	77	79	83	78	82	83	<b>80</b>
% Pts with Mean Hgb 11-12.0 g/dL <sup>^</sup>	37	34	34	39	37	33	36	39	32	34	28	43	33	38	34	40	39	38	<b>36</b>
% Pts with Mean Hgb < 10g/dL	5	8	7	7	6	7	8	5	6	5	6	7	7	6	5	6	5	6	<b>6</b>
Median wkly IV EPO dose units/kg/wk	200.7	232.7	216.9	207.0	217.3	220.5	211.9	206.1	200.6	220.8	189.0	186.5	219.1	181.2	189.4	181.2	170.3	189.7	<b>201.2</b>
Median wkly SCEPO dose units/kg/wk	154.4	164.7	183.1	108.0	178.2	102.7	235.4	403.1	209.2	169.3	111.6	154.9	137.1	115.9	103.6	166.7	144.9	156.7	<b>157.7</b>
% Pts Rx'd <sup>^</sup> SCEPO	4	4	10	*	3	*	3	*	11	4	4	6	7	12	6	11	13	16	<b>7</b>
<b>Iron Mgmt.</b>	<b>Net 1</b>	<b>Net 2</b>	<b>Net 3</b>	<b>Net 4</b>	<b>Net 5</b>	<b>Net 6</b>	<b>Net 7</b>	<b>Net 8</b>	<b>Net 9</b>	<b>Net 10</b>	<b>Net 11</b>	<b>Net 12</b>	<b>Net 13</b>	<b>Net 14</b>	<b>Net 15</b>	<b>Net 16</b>	<b>Net 17</b>	<b>Net 18</b>	<b>US</b>
% Pts with Mean TSAT ≥ 20%	79	79	80	81	83	85	80	78	74	82	81	75	81	83	82	72	78	87	<b>81</b>
Median TSAT %	26.7	28.0	26.3	27.0	27.0	27.7	27.3	25.7	25.7	28.3	27.7	24.8	27.0	28.6	26.6	24.0	26.3	29.8	<b>27.0</b>
% Pts with Mean Ferritin ≥ 100 ng/mL	92	92	91	94	91	94	96	95	94	95	94	95	96	95	93	97	94	94	<b>94</b>
Median Ferritin ng/mL	495	537	482	496	461	556	589	572	566	598	493	510	573	580	466	460	470	603	<b>526</b>
% Pts Rx'd <sup>^</sup> IV Iron	65	64	73	65	69	66	66	67	70	65	66	64	66	67	65	64	55	56	<b>65</b>

<sup>^</sup> Among those patients prescribed Epoetin Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**2004 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES (cont.)  
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

Albumin	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
% Pts with Mean serum albumin ≥ 4.0/3.7g/dL (BCG/BCP) <sup>^^</sup>	32	40	33	35	33	40	37	43	40	45	37	34	40	43	34	31	42	41	39
% Pts with Mean serum albumin ≥ 3.5/3.2g/dL (BCG/BCP)	80	78	77	77	82	85	79	83	78	82	80	79	83	84	82	82	82	85	81
Median serum <b>BCG</b> albumin (g/dL)	3.8	3.9	3.8	3.8	3.8	3.9	3.9	3.9	3.9	3.9	3.9	3.8	3.9	3.9	3.9	3.8	3.9	3.9	3.9
Median serum <b>BCP</b> albumin (g/dL)	3.7	3.6	3.2	3.3	*	3.6	4.0	*	3.1	3.5	3.5	3.7	3.7	3.8	3.5	3.4	*	3.1	3.5

<sup>^^</sup>BCG/BCP-Brom cresol Green/Brom cresol Purple Laboratory Methods

\* Value suppressed because n ≤ 10

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

### Appendix 8. 2004 ESRD CPM Outcome Comparison Tool – Adult In-Center Hemodialysis Patients – National and Network Data are from October – December 2003.

Enter your Network data from Appendix 8 and use this tool to document and compare your facility outcomes to the national data and your Network data.

	US	Network	Facility
<b>Adequacy of Dialysis</b>			
Percent of patients with a mean spKt/V $\geq 1.2$	91%		
Mean ( $\pm$ SD) spKt/V	1.53 ( $\pm$ 0.26)		
Mean ( $\pm$ SD) blood pump flow rate (mL/minute)	395 ( $\pm$ 64)		
Mean ( $\pm$ SD) dialysis session length (minutes)	216 ( $\pm$ 30)		
<b>Vascular Access</b>			
Percent of prevalent patients dialyzed with an AVF	35%		
Percent of incident patients dialyzed with an AVF	35%		
Percent of prevalent patients dialyzed with an AV graft	38%		
Percent of prevalent patients dialyzed with a catheter	27%		
Percent of prevalent patients dialyzed with a catheter $\geq 90$ days	20%		
<b>Anemia Management</b>			
Percent of patients with mean Hgb $\geq 11.0$ g/dL	80%		
Percent of targeted† patients with mean Hgb 11.0 – 12.0 g/dL	36%		
Percent of patients with mean Hgb $< 10.0$ g/dL	6%		
Mean ( $\pm$ SD) Hgb (g/dL)	11.9 ( $\pm$ 1.2)		
Mean ( $\pm$ SD) weekly Epoetin dose (units/kg/week)			
IV	271.3 ( $\pm$ 251.8)		
SC	206.2 ( $\pm$ 184.8)		
Percent of patients* prescribed SC Epoetin	7%		
Percent of patients with mean TSAT $\geq 20\%$	81%		
Mean ( $\pm$ SD) TSAT (%)	29.3 ( $\pm$ 12.1)		
Percent of patients with mean serum ferritin concentration $\geq 100$ ng/mL	94%		
Mean ( $\pm$ SD) serum ferritin concentration (ng/mL)	596 ( $\pm$ 419)		
Percent of patients prescribed IV iron	65%		
<b>Serum Albumin</b>			
Percent of patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP)	39%		
Percent of patients with mean serum albumin $\geq 3.5/3.2$ g/dL (BCG/BCP)	81%		
Mean ( $\pm$ SD) serum albumin (g/dL)			
BCG	3.8 ( $\pm$ 0.4)		
BCP	3.5 ( $\pm$ 0.5)		

† See appendix 1 for complete definition of targeted patients for this CPM.

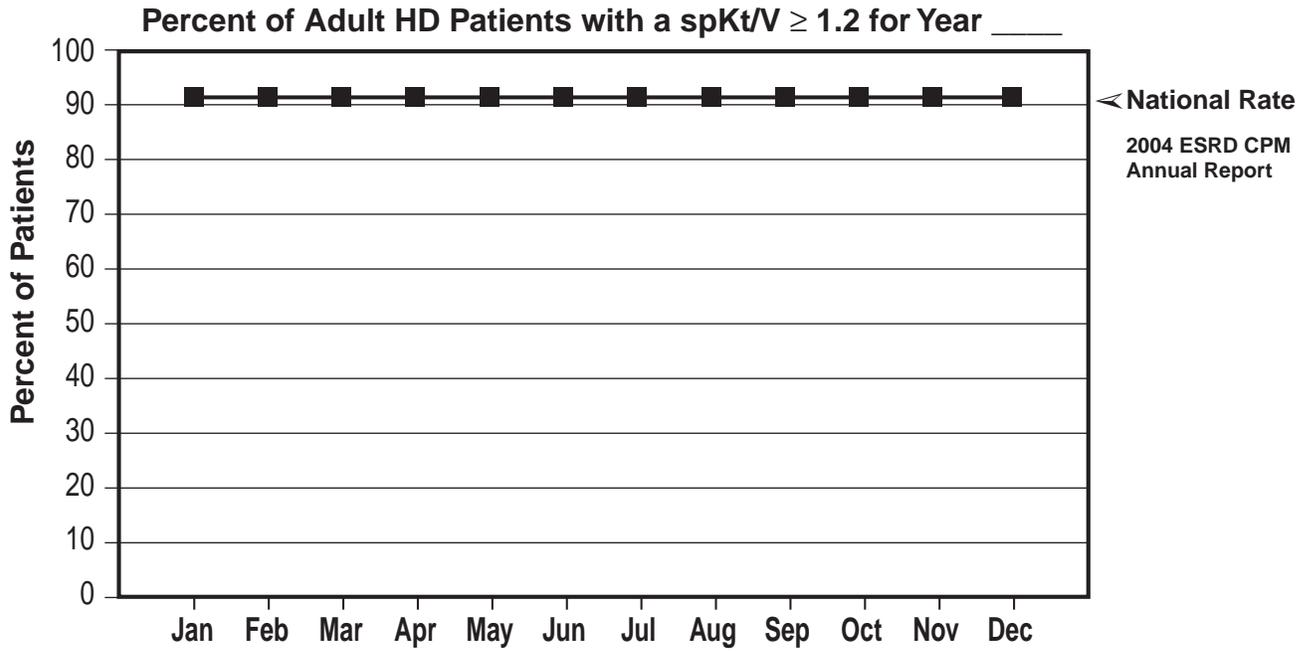
\* Among those patients prescribed Epoetin.

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

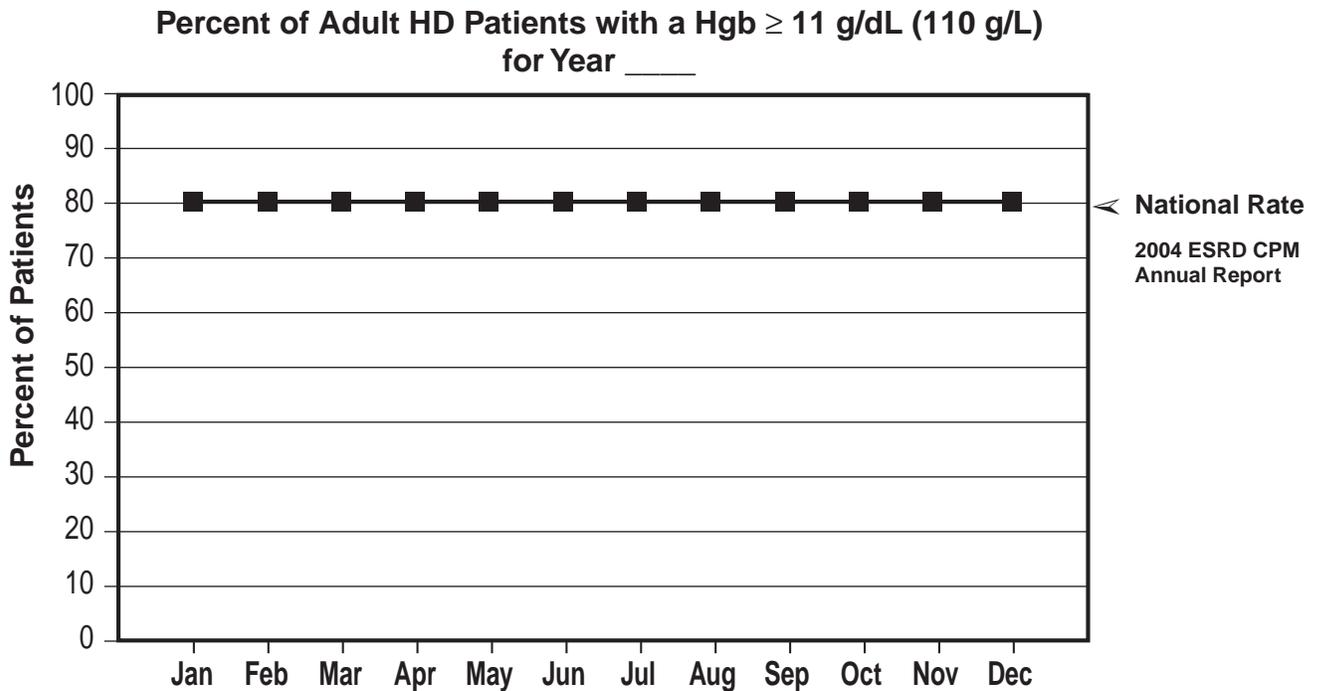
Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

CUT ALONG THIS LINE

Use the following chart to plot monthly the percent of adult HD patients in your unit that have a spKt/V  $\geq 1.2$  (Nation = 91%). Post the chart in the facility for all to see.



Use the following chart to plot monthly the percent of adult HD patients in your unit that have a Hgb  $\geq 11$  g/dL (110 g/L) (Nation = 80%). Post the chart in the facility for all to see.



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### Appendix 9. 2004 ESRD CPM Outcome Comparison Tool – Adult Peritoneal Dialysis Patients – National Data are from October 2003 – March 2004.

Use this tool to document and compare your facility outcomes to the national data.

	US	Facility
<b>Adequacy of Dialysis</b>		
Percent of patients measured for adequacy at least once during the six month study period (both weekly Kt/V <sub>urea</sub> and weekly creatinine clearance measured)	86%	
Percent of CAPD patients with mean weekly Kt/V <sub>urea</sub> ≥ 2.0	67%	
Mean (± SD) weekly Kt/V <sub>urea</sub> for CAPD patients	2.28 (±0.64)	
Percent of Cycler patients with a daytime dwell with mean weekly Kt/V <sub>urea</sub> ≥ 2.1	59%	
Mean (± SD) weekly Kt/V <sub>urea</sub> for Cycler patients with a daytime dwell	2.29 (±0.60)	
Percent of Cycler patients without a daytime dwell with mean weekly Kt/V <sub>urea</sub> ≥ 2.2	56%	
Mean (± SD) weekly Kt/V <sub>urea</sub> for Cycler patients without a daytime dwell	2.39 (± 0.73)	
<b>Anemia Management</b>		
Percent of patients with mean Hgb ≥ 11.0 g/dL	82%	
Percent of targeted <sup>†</sup> patients with mean Hgb 11.0 – 12.0 g/dL	39%	
Percent of patients with mean Hgb < 10.0 g/dL	5%	
Mean (± SD) Hgb (g/dL)	12.0 (± 1.3)	
Percent of patients* prescribed SC Epoetin	98%	
Percent of patients with mean TSAT ≥ 20%	85%	
Mean (± SD) TSAT (%)	29.9 (± 10.7)	
Percent of patients with mean serum ferritin ≥ 100 ng/mL	88%	
Mean (± SD) serum ferritin concentration (ng/mL)	453 (± 405)	
Percent of patients prescribed IV iron	23%	
<b>Serum Albumin</b>		
Percent of patients with mean serum albumin ≥ 4.0/3.7 g/dL (BCG/BCP)	20%	
Percent of patients with mean serum albumin ≥ 3.5/3.2 g/dL (BCG/BCP)	63%	
Mean (± SD) serum albumin (gm/dL)		
BCG	3.6 (± 0.5)	
BCP	3.3 (± 0.5)	

<sup>†</sup> See appendix 1 for complete definition of targeted patients for this CPM.

\* Among those patients prescribed Epoetin.

Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

Use the following chart to plot monthly:

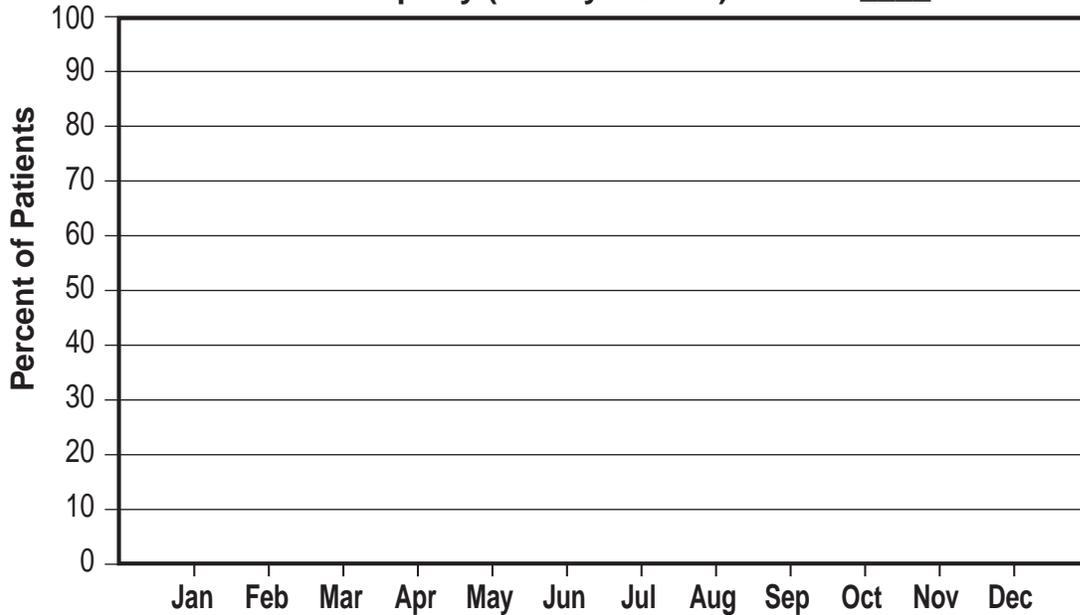
The % of adult CAPD patients in your unit that have a  $Kt/V_{urea} \geq 2.0$  (Nation = 67%).

The % of adult Cycler patients with a daytime dwell that have a  $Kt/V_{urea} \geq 2.1$  (Nation = 59%);

The % of adult Cycler patients without a daytime dwell that have a  $Kt/V_{urea} \geq 2.2$  (Nation = 56%).

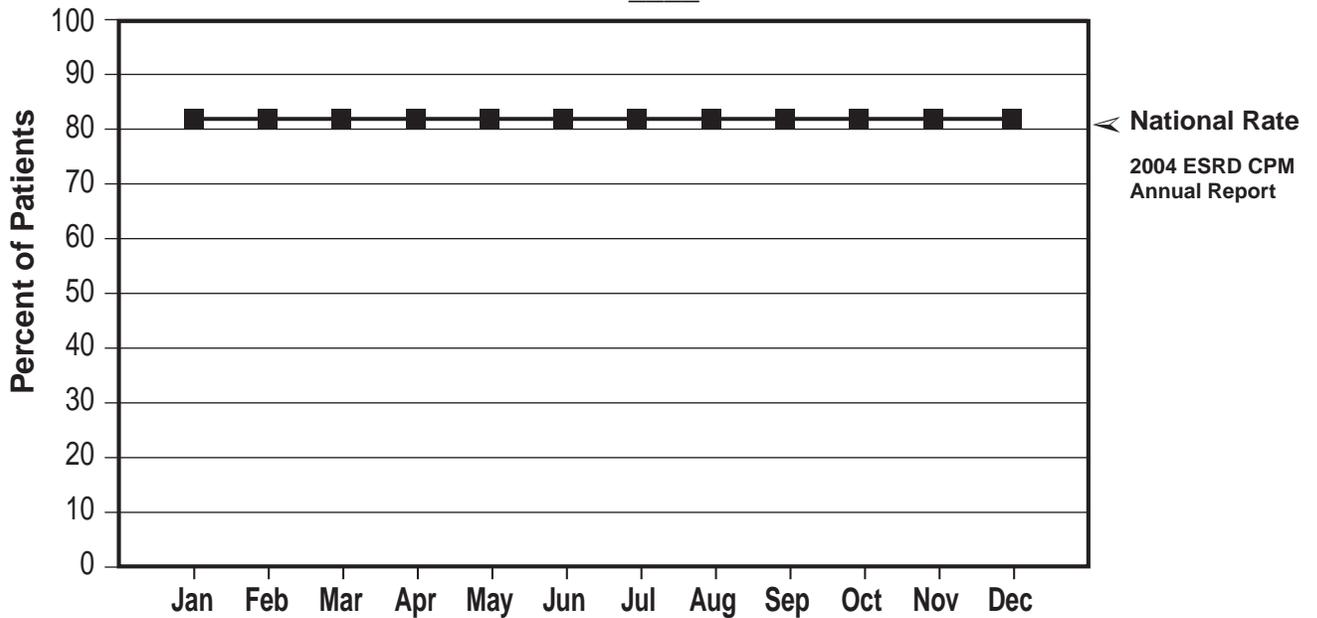
Post the chart in the facility for all to see.

**Percent of Adult PD Patients Meeting NKF-K/DOQI Guidelines for Adequacy (weekly  $Kt/V_{urea}$ ) for Year \_\_\_\_\_**



Use the following chart to plot monthly the percent of adult PD patients in your unit that have a Hgb  $\geq 11$  g/dL (110 g/L) (Nation = 82%). Post the chart in the facility for all to see.

**Percent of Adult PD Patients with a Hgb  $\geq 11$  g/dL (110 g/L) for Year \_\_\_\_\_**



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