

2005 ANNUAL REPORT ESRD CLINICAL PERFORMANCE MEASURES PROJECT

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

DECEMBER 2005



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



Data on adult and pediatric in-center hemodialysis patients are from October–December 2004

Data on adult and pediatric peritoneal dialysis patients are from October 2004–March 2005

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Note: The clinical data collected for the 2005 ESRD Clinical Performance Measures Project were from the time period of October–December 2004 for the in-center hemodialysis patients and October 2004–March 2005 for the peritoneal dialysis patients.

2006 Data Collection Effort

In 2006, we will again collect data for the ESRD Clinical Performance Measures on a national sample of adult in-center hemodialysis and peritoneal dialysis patients and all pediatric in-center hemodialysis and peritoneal dialysis patients.

Any questions about the Project may be addressed to your ESRD Network staff or to members of the ESRD Clinical Performance Measures Quality Improvement Workgroup (APPENDICES 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/CPMProject.

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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

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

I. INTRODUCTION

The ESRD Clinical Performance Measures (CPM) Project, now in its twelfth year, is a national effort led by the Centers for Medicare & Medicaid Services (CMS) 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 2005 ESRD CPM Annual Report describes the findings of several important clinical measures and/or characteristics of a nationally representative random sample of adult (aged ≥ 18 years) in-center hemodialysis patients and peritoneal dialysis patients. This report also includes the findings for all in-center hemodialysis and peritoneal dialysis patients aged < 18 years.

The most recent data described in this Report are from the 2005 study period which includes the months of October-December 2004 for the in-center hemodialysis patients and October 2004-March 2005 for the peritoneal dialysis patients. This Report also compares the 2005 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/CPMProject. 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 seven major sections: **Background and Project Methods, Clinical Performance Measures (CPMs), Other Significant Findings and Trends, Adult In-Center Hemodialysis Patients, Adult Peritoneal Dialysis Patients, Pediatric In-Center Hemodialysis (aged < 18) and Pediatric Peritoneal Dialysis Patients (aged < 18)**. The lists of tables and figures have been moved to the back of the Report as Section X (page 64).

This Report also contains some features or tools to assist dialysis providers in using the information from this project. Appendices 8 and 9 (pages 101 and 103) contain tear out ESRD 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 2004 (national peritoneal dialysis findings are from the time period October 2004 – March 2005), 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 **ESRD Clinical Performance Measures (CPMs)** section beginning on page 12, has a short summary of each CPM collected for this project as well as a brief summary of the 2005 CPM findings. Appendix 1 (page 70) provides a more detailed description of each CPM.

The **Other Significant Findings and Trends** section beginning on page 16, provides highlights of important findings from the 2005 ESRD CPM Project.

The **Adult In-Center Hemodialysis Patients, Adult Peritoneal Dialysis Patients, and Pediatric In-Center Hemodialysis Patients** sections describe the findings for each cohort for the 2005 study period and compare these findings to previous study periods. The **Pediatric Peritoneal Dialysis Patients** section is new this year, and describes findings for this cohort for the 2005 study period.

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) (2-5). 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, and pediatric peritoneal dialysis patients.

Pediatric In-Center Hemodialysis and Peritoneal Dialysis Patients

Although there are no CPMs established for the pediatric age group, demographic and clinical information from October-December 2004 were collected on all hemodialysis patients aged < 18 years and from October 2004-March 2005 on all peritoneal dialysis patients aged < 18 years in the U.S. in order to describe several core indicators of dialysis care. These core indicators included dialysis clearance, vascular access (hemodialysis only), 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 338 per million population (8). As of December 31, 2004, there were 320,404 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 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 (13-16).

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/esrdQualityImproveInit/08_Archives.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 2005 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 and for the first time, findings on all pediatric (aged < 18 years) peritoneal dialysis patients are 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 2004 and adult and pediatric peritoneal dialysis patients for the time period October 2004–March 2005.

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 seventh data collection effort for the ESRD CPMs which was conducted in 2005. Data were collected from October–December 2004 for adult and pediatric in-center hemodialysis patients, and from October 2004–March 2005 for adult and pediatric 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 2005, a listing of adult (aged ≥ 18 years as of September 30, 2004) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 2004, 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, 2004. The final sample consisted of 8,885 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 1,432 peritoneal dialysis patients.

All pediatric (aged < 18 years) in-center hemodialysis patients in the U.S. ($n = 781$) and all pediatric peritoneal dialysis patients in the U.S. ($n = 817$) were included in the 2005 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 the data collection forms that were downloaded by Networks from the Network Standard Information Management System (SIMS). 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.

Electronic data for some of the data elements 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). The electronically submitted data were printed onto paper forms, and these paper forms were sent to facilities for sampled patients. Facility staff were instructed to supply the data not already provided on the paper form. 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 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 any time during October, November, and December 2004. Clinical information contained in the medical records was also abstracted for each patient in the adult peritoneal dialysis sample and for all pediatric peritoneal dialysis patients who were receiving peritoneal dialysis at any time during October 2004–March 2005. The completed data collection forms were then forwarded to the appropriate Network, where data were reviewed for acceptability and manually entered into SIMS.

In October 2005, each Network completed data entry into SIMS. CMS's contractor, Computer Sciences Corporation (CSC) aggregated the data and then submitted the data to CMS for 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 file 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 8,479 of the 8,885 patients from the sample (response rate = 95%) (TABLE 1). In the vascular access section, some findings are presented for incident patients (see definition of incident patients, Table 9 page 28) 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 U.S. hemodialysis population (8). Data regarding erythropoietin stimulating agent (ESA) use, serum ferritin concentrations, transferrin saturation, iron use, dialyzer K_Uf (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).

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 K_Uf, 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 na-

tional results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

TABLE 1: Number of adult in-center hemodialysis patients in each Network in December 2004, sample size and response rate for the 2005 ESRD CPM Project.

| Network | # HD Patients Dec 2003 | Sample Size | # Acceptable Forms [^] | Response Rate % |
|--------------|------------------------|--------------|---------------------------------|-----------------|
| 1 | 9,579 | 487 | 452 | 92.8 |
| 2 | 20,730 | 498 | 474 | 95.2 |
| 3 | 12,361 | 492 | 479 | 97.4 |
| 4 | 13,251 | 492 | 465 | 94.5 |
| 5 | 17,450 | 496 | 470 | 94.8 |
| 6 | 27,283 | 500 | 477 | 95.4 |
| 7 | 16,924 | 496 | 468 | 94.4 |
| 8 | 16,057 | 495 | 476 | 96.2 |
| 9 | 20,477 | 498 | 475 | 95.4 |
| 10 | 11,849 | 491 | 469 | 95.5 |
| 11 | 17,772 | 496 | 463 | 93.3 |
| 12 | 10,391 | 488 | 446 | 91.4 |
| 13 | 12,252 | 491 | 470 | 95.7 |
| 14 | 25,117 | 499 | 486 | 97.4 |
| 15 | 12,782 | 491 | 479 | 97.6 |
| 16 | 7,243 | 482 | 470 | 97.5 |
| 17 | 14,845 | 494 | 476 | 96.4 |
| 18 | 23,228 | 499 | 484 | 97.0 |
| Total | 289,591 | 8,885 | 8,479 | 95.4 |

[^] 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 2004 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 97% 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.

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 2004–March 2005, and that at least one hemoglobin and at least one serum albumin value were reported during the six-month study period. Of the 1,432 patients sampled,

TABLE 2: Characteristics of adult in-center hemodialysis patients in the 2005 ESRD CPM Project compared to those of all in-center hemodialysis patients in the U.S. in 2003.

| Patient Characteristic | 2005 CPM Sample for Analysis | | All U.S. in 2003* | |
|-------------------------------------|------------------------------|------------|-------------------|------------|
| | # ^ | % | # in 1,000s | % |
| TOTAL | 8,479 | 100 | 296.6 | 100 |
| GENDER | | | | |
| Men | 4,558 | 54 | 160.1 | 54 |
| Women | 3,921 | 46 | 136.7 | 46 |
| RACE | | | | |
| American Indian/ Alaska Native | 150 | 2 | 4.3 | 1 |
| Asian/Pacific Islander | 351 | 4 | 12.1 | 4 |
| Black | 3,013 | 36 | 113.6 | 38 |
| White | 4,590 | 54 | 161.6 | 54 |
| Other/Unknown | 375 | 4 | 5.1 | 2 |
| ETHNICITY | | | | |
| Hispanic | 1,048 | 12 | 41.8 | 14 |
| Non-Hispanic | 7,313 | 86 | 255.0 | 86 |
| Unknown | 118 | 1 | 0 | 0 |
| AGE GROUP (years) | | | | |
| 18-49 | 1,844 | 22 | 66.4 ** | 22 |
| 50-59 | 1,816 | 21 | 60.4 | 20 |
| 60-64 | 980 | 12 | 33.9 | 11 |
| 65-69 | 968 | 11 | 35.1 | 12 |
| 70-79 | 1,882 | 22 | 66.3 | 22 |
| 80+ | 989 | 12 | 33.4 | 11 |
| CAUSE of ESRD | | | | |
| Diabetes mellitus | 3,599 | 42 | 126.5 | 43 |
| Hypertension | 2,187 | 26 | 84.8 | 29 |
| Glomerulonephritis | 890 | 10 | 33.5 | 11 |
| Other/Unknown | 1,803 | 21 | 52.0 | 18 |
| DURATION of DIALYSIS (years) | | | | |
| <0.5 | 1,024 | 12 | | |
| 0.5-0.9 | 982 | 12 | | |
| 1.0-1.9 | 1,588 | 19 | | |
| 2.0-2.9 | 1,188 | 14 | | |
| 3.0-3.9 | 941 | 11 | | |
| 4.0+ | 2,709 | 32 | | |

*USRDS: 2005 Annual Data Report, Bethesda, MD, National Institutes of Health, 2005. Table D.11

^ Subgroup totals may not equal 8,479 due to missing data.

** For ages 20-49 years

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

1,337 patients were included in the sample for analysis (93% response rate) (TABLE 3). Selected patient characteristics 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_{urea}, 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.

TABLE 3: Number of adult peritoneal dialysis patients in each Network in December 2004, sample size and response rate for the 2005 ESRD CPM Project.

| Network | # Peritoneal Dialysis Patients in December 2004 | Sample Size | # Acceptable Forms^ | Response Rate % |
|--------------|---|--------------|---------------------|-----------------|
| 1 | 1,123 | 55 | 46 | 83.6 |
| 2 | 1,220 | 82 | 78 | 95.1 |
| 3 | 945 | 60 | 58 | 96.7 |
| 4 | 889 | 51 | 51 | 100.0 |
| 5 | 1,544 | 91 | 89 | 97.8 |
| 6 | 2,449 | 142 | 126 | 88.7 |
| 7 | 1,312 | 81 | 75 | 92.6 |
| 8 | 1,725 | 88 | 77 | 87.5 |
| 9 | 2,025 | 102 | 94 | 92.2 |
| 10 | 1,153 | 63 | 59 | 93.7 |
| 11 | 1,647 | 99 | 92 | 92.9 |
| 12 | 1,227 | 45 | 38 | 84.4 |
| 13 | 1,110 | 47 | 43 | 91.5 |
| 14 | 1,918 | 96 | 95 | 99.0 |
| 15 | 1,168 | 62 | 60 | 96.8 |
| 16 | 943 | 61 | 60 | 98.4 |
| 17 | 1,681 | 98 | 89 | 90.8 |
| 18 | 1,965 | 109 | 107 | 98.2 |
| Total | 26,044 | 1,432 | 1,337 | 93.4 |

^ 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.

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 781 pediatric hemodialysis patients, 692 patients were included in the sample for analysis (89%). Selected patient characteristics of this sample for analysis are shown in Table 5.

TABLE 4: Characteristics of adult peritoneal dialysis patients in the 2005 ESRD CPM Project compared to those of all peritoneal dialysis patients in the U.S. in 2003.

| Patient Characteristic | 2005 CPM Sample for Analysis | | All U.S. in 2003* | |
|-------------------------------------|------------------------------|------------|-------------------|------------|
| | # ^ | % | # in 1,000s | % |
| TOTAL | 1,337 | 100 | 25.9 | 100 |
| GENDER | | | | |
| Men | 683 | 51 | 13.2 | 51 |
| Women | 654 | 49 | 12.7 | 49 |
| RACE | | | | |
| American Indian/ Alaska Native | 18 | 1 | 0.3 | 1 |
| Asian/Pacific Islander | 70 | 5 | 1.4 | 5 |
| Black | 339 | 25 | 6.8 | 26 |
| White | 856 | 64 | 16.9 | 65 |
| Other/Unknown | 54 | 4 | 0.4 | 2 |
| ETHNICITY | | | | |
| Hispanic | 151 | 11 | 3.4 | 13 |
| Non-Hispanic | 1,171 | 88 | 22.5 | 87 |
| Other/Unknown | 15 | 1 | 0 | 0 |
| AGE GROUP (years) | | | | |
| 18-49 | 479 | 36 | 8.5 | 33 |
| 50-59 | 328 | 25 | 5.9 | 23 |
| 60-64 | 156 | 12 | 2.8 | 11 |
| 65-69 | 132 | 10 | 2.6** | 10 |
| 70-79 | 184 | 14 | 3.9 | 15 |
| 80+ | 58 | 4 | 1.2 | 5 |
| CAUSE of ESRD | | | | |
| Diabetes Mellitus | 466 | 35 | 9.0 | 35 |
| Hypertension | 275 | 21 | 6.0 | 23 |
| Glomerulonephritis | 208 | 16 | 4.9 | 19 |
| Other/Unknown | 388 | 29 | 5.9 | 23 |
| DURATION of DIALYSIS (years) | | | | |
| <0.5 | 183 | 14 | | |
| 0.5-0.9 | 202 | 15 | | |
| 1.0-1.9 | 304 | 23 | | |
| 2.0+ | 194 | 15 | | |
| 3.0-3.9 | 123 | 9 | | |
| 4.0+ | 324 | 24 | | |

*USRDS: 2005 Annual Data Report, Bethesda, MD, National Institutes of Health, 2005. Table D.11

^ Subgroup totals may not equal 1,337 due to missing data.

** For ages 20-49 years

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 at least once during the six-month study period for hemoglobin and serum albumin.

Two or more values were available for 97% of patients for hemoglobin and 97% for serum albumin by either BCG or BCP methods. Three hemoglobin values were available for 85% of patients; three serum albumin values were available for 85% of patients.

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 or darbepoetin 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 in-center hemodialysis patients aged < 18 years in the U.S. Only national aggregate data are reported. No Network-specific or facility-specific analyses were conducted.

Pediatric Peritoneal Dialysis Patients

For the first time this study year, clinical and demographic information was collected on all pediatric peritoneal dialysis patients aged < 18 years. Inclusion of a record for analysis required that the patient received peritoneal dialysis at least one month during the time period October 2004-March 2005 and that at least one hemoglobin value and at least one serum albumin value were reported during the six-month study period. Of the 817 pediatric peritoneal dialysis patients identified, 761 (93%) were included in the sample for analysis (TABLE 6).

For this Report, each patient's mean value for the six-month study period was determined from available data for the following items: weekly Kt/V_{urea}, weekly creatinine clearance, hemoglobin, 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 were collected on all pediatric peritoneal dialysis 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 2004 for the adult in-center hemodialysis patients, and October 2004–March 2005 for the adult peritoneal dialysis patients. This report also describes findings on clinical parameters of care for pediatric in-center hemodialysis and peritoneal dialysis patients in the U.S. for October–December 2004 (hemodialysis) and October 2004–March 2005 (peritoneal dialysis) in Section VII and VIII, respectively.

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 2005 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 2005 ESRD CPM Project.

| Patient Characteristic | 2005 CPM Project | |
|-------------------------------------|------------------|------------|
| | #^ | % |
| TOTAL | 692 | 100 |
| GENDER | | |
| Males | 380 | 55 |
| Females | 312 | 45 |
| RACE | | |
| American Indian/ Alaska Native | * | * |
| Asian/Pacific Islander | 21 | 3 |
| Black | 237 | 34 |
| White | 372 | 54 |
| Other/Unknown | 52 | 8 |
| ETHNICITY | | |
| Hispanic | 213 | 31 |
| Non-Hispanic | 469 | 68 |
| Other/Unknown | * | * |
| AGE GROUP (years) | | |
| 0-4 | 44 | 6 |
| 5-9 | 74 | 11 |
| 10-14 | 233 | 34 |
| 15 to <18 | 341 | 49 |
| CAUSE of ESRD | | |
| Congenital/Urologic | 175 | 25 |
| Glomerulonephritis | 115 | 17 |
| FSGS^^ | 101 | 15 |
| SLE^^^ | 37 | 5 |
| Cystic Disease | 22 | 3 |
| Hypertension | 21 | 3 |
| Other/Unknown | 221 | 32 |
| DURATION of DIALYSIS (years) | | |
| <0.5 | 146 | 21 |
| 0.5-0.9 | 123 | 18 |
| 1.0-1.9 | 149 | 22 |
| 2.0-2.9 | 64 | 9 |
| 3.0-3.9 | 38 | 5 |
| 4.0+ | 167 | 24 |

^Subgroup totals may not equal 692 due to missing data.

^^FSGS = Focal and Segmental Glomerulosclerosis

^^^SLE = Systemic Lupus Erythematosus

*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 2004 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 90% of patients for hemoglobin and 91% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 83% 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 89%. Monthly paired pre- and post-dialysis BUN values were available for 77% of patients.

TABLE 6: Characteristics of pediatric (aged < 18 years) peritoneal dialysis patients in the 2005 ESRD CPM Project.

| Patient Characteristic | 2005 CPM Project | |
|-------------------------------------|------------------|------------|
| | #^ | % |
| TOTAL | 761 | 100 |
| GENDER | | |
| Males | 427 | 56 |
| Females | 334 | 44 |
| RACE | | |
| American Indian/ Alaska Native | * | * |
| Asian/Pacific Islander | 22 | 3 |
| Black | 177 | 23 |
| White | 500 | 66 |
| Other/Unknown | 59 | 8 |
| ETHNICITY | | |
| Hispanic | 207 | 27 |
| Non-Hispanic | 542 | 71 |
| Other/Unknown | 12 | 2 |
| AGE GROUP (years) | | |
| 0-4 | 163 | 21 |
| 5-9 | 138 | 18 |
| 10-14 | 274 | 36 |
| 15 to < 18 | 186 | 24 |
| CAUSE of ESRD | | |
| Congenital/Urologic | 253 | 33 |
| Glomerulonephritis | 96 | 13 |
| FSGS | 117 | 15 |
| SLE | 13 | 2 |
| Cystic Disease | 35 | 5 |
| Hypertension | * | * |
| Other/Unknown | 247 | 32 |
| DURATION of DIALYSIS (years) | | |
| < 0.5 | 165 | 22 |
| 0.5-0.9 | 160 | 21 |
| 1.0-1.9 | 179 | 24 |
| 2.0-2.9 | 92 | 12 |
| 3.0-3.9 | 41 | 5 |
| 4.0+ | 122 | 16 |

^ Subgroup totals may not equal 761 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 at least once during the six-month study period for hemoglobin and serum albumin.

Two or more values were available for 97% of patients for hemoglobin and 97% for serum albumin by either BCG or BCP methods. Three hemoglobin values were available for 84% of patients; three serum albumin values were available for 83% 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 (p. 70).

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_{urea}) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 1, p. 71).

CPM III. For patients on continuous ambulatory peritoneal dialysis (CAPD), the delivered peritoneal dialysis dose is a total Kt/V_{urea} of at least 2.0 per week and a total creatinine clearance (CrCl) of at least 60 L/week/1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

For CCPD patients (cycler patients with a daytime dwell), the weekly delivered peritoneal dialysis dose is a total Kt/V_{urea} of at least 2.1 and a weekly total creatinine clearance of at least 63L/week/1.73 m² 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_{urea} of at least 2.2 and a weekly total creatinine clearance of at least 66 L/week/1.73 m² OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

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 ≥ 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, p. 72 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 ≥ 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 ≥ 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 ≥ 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 ≥ 100 ng/mL, and the percents of patients prescribed subcutaneous (SC) epoetin or IV iron are profiled.

Information was collected on epoetin and darbepoetin use 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 (p. 70) for the specific inclusion and exclusion criteria for each CPM.

NOTE: Highlights of important findings from the 2005 ESRD CPM Project may be found on the following pages:

CPM highlights for adult hemodialysis patients, page 14

CPM highlights for adult peritoneal dialysis patients, page 15

Selected significant findings for adult in-center hemodialysis patients, page 19

Selected significant findings for adult peritoneal dialysis patients, page 20

Selected significant findings for pediatric in-center hemodialysis patients, page 21

Selected significant findings for pediatric peritoneal dialysis patients, page 22

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 2005 ESRD PROJECT

Random Sample of Adult In-Center Hemodialysis (HD) Patients (n=8,479 sample for analysis) The data are from OCT-DEC 2004:

HD Adequacy

- 83% of patients had monthly adequacy measurements performed (HD Adequacy CPM I)
- 76% of patients had their delivered spKt/V calculated using either UKM or the Daugirdas II formula (26) (HD Adequacy CPM II)
- 95% of patients on dialysis for 6 months or more and dialyzing three times a week had a mean delivered adequacy dose of spKt/V ≥ 1.2 calculated using the Daugirdas II formula (HD Adequacy CPM III)

Vascular Access (VA)

- 37% of incident patients were dialyzed using an AV fistula (AVF) (VA CPM I) (FIGURE 30)
- 39% of prevalent patients were dialyzed using an AVF (VA CPM I) (FIGURES 2, 30)
- 21% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer (VA CPM II) (FIGURE 2)

- 67% of prevalent patients with an AV graft were routinely monitored for the presence of stenosis (VA CPM III)

Anemia Management (AM)

- 34% of targeted patients prescribed epoetin had a mean hemoglobin 11.0-12.0 g/dL (110-120 g/L) (AM CPM I)
- 95% of patients who met the inclusion criteria¹ had at least one documented transferrin saturation value and one documented serum ferritin concentration value during the study period (AM CPM IIa)
- 80% of patients who met the inclusion criteria¹ had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration ≥ 100 ng/mL during the study period (AM CPM IIb)
- 82% of patients who met the inclusion criteria¹ were prescribed intravenous iron in at least one month during the study period (AM CPM III)

¹See Appendix 1 for a description of the inclusion and exclusion criteria.

| ESRD CPM Trends (percent of patients meeting the CPMs) ¹ | Year | | | | | | |
|---|-----------------|------|------|------|------|-------------------|-----------|
| | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 ⁴ | 2004 |
| HD Adequacy | | | | | | | |
| HD Adequacy CPM I (monthly measurement of delivered HD dose) | 79 | 76 | 80 | 82 | 83 | 83 | 83 |
| HD Adequacy CPM II (method of measurement of delivered HD dose) | 99 ⁵ | 50 | 52 | 68 | 67 | 83 | 76 |
| HD Adequacy CPM III (mean delivered HD dose ≥ 1.2) | 85 | 90 | 91 | 92 | 92 | 94 | 95 |
| Vascular Access | | | | | | | |
| Vascular Access CPM Ia (incident patients with an AVF ² as access) | 26 | 28 | 27 | 29 | 27 | 35 | 37 |
| Vascular Access CPM Ib (prevalent patients with an AVF as access) | 26 | 27 | 30 | 31 | 33 | 35 | 39 |
| Vascular Access CPM II (dialyzed with a chronic catheter ³) | 14 | 14 | 17 | 19 | 21 | 20 | 21 |
| Vascular Access CPM III (AV graft was routinely monitored for stenosis) | 37 | 45 | 47 | 51 | 61 | 77 | 67 |
| Anemia Management | | | | | | | |
| Anemia CPM I (mean Hgb 11-12 g/dL) | 36 | 36 | 38 | 38 | 36 | 36 | 34 |
| Anemia CPM IIa (iron stores assessed for anemic patients or patients prescribed Epoetin) | 90 | 89 | 91 | 92 | 94 | 96 | 95 |
| Anemia CPM IIb (iron stores maintained at K/DOQI targets) | 67 | 66 | 71 | 75 | 78 | 81 | 80 |
| Anemia CPM III (administration of IV iron to anemic patients) | 63 | 67 | 73 | 77 | 79 | 79 | 82 |

¹ See Appendix 1 for a description of the inclusion and exclusion criteria.

² Arteriovenous fistula

³ For 90 days or longer

⁴ First year for Large Dialysis Organization (LDO) electronic data submission.

⁵ For 1998 only, accepted HD dose calculated using urea kinetic modeling (UKM), Daugirdas II, or urea reduction ratio (URR); for all subsequent years, only UKM or Daugirdas II accepted.

NOTE: Please note that when a single year such as 2004 is used in displaying data, it refers to October, November, and December of that year for the hemodialysis patients.

CPM HIGHLIGHTS FROM THE NATIONAL 2005 ESRD PROJECT

**Random Sample of Adult Peritoneal Dialysis (PD) Patients (n=1,337 sample for analysis)
The data are from OCT 2004–MAR 2005:**

PD Adequacy

- 82% 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)
- 41% of patients had their total solute clearance for urea and creatinine calculated in a standard way¹ (PD Adequacy CPM II) (FIGURE 3)
- 73% of CAPD patients had a mean weekly Kt/V_{urea} of ≥ 2.0 and a mean weekly creatinine clearance $\geq 60\text{L/week}/1.73\text{m}^2$ 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, 48)
- 59% of Cycler patients with a daytime dwell had a mean weekly Kt/V_{urea} of ≥ 2.1 and a mean weekly creatinine clearance $\geq 63\text{L/week}/1.73\text{m}^2$ 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, 48)
- 58% of Cycler patients without a daytime dwell had a mean Kt/V_{urea} of ≥ 2.2 and a mean weekly creatinine clearance

$\geq 66\text{L/week}/1.73\text{m}^2$ 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, 48)

Anemia Management (AM)

- 33% of targeted patients prescribed epoetin had a mean hemoglobin between 11.0-12.0 g/dL (110-120 g/L) (AM CPM I)
- 77% of patients who met the inclusion criteria² 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)
- 82% of patients who met the inclusion criteria² for this CPM had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration $\geq 100\text{ng/mL}$ during the six-month study period (AM CPM IIb)
- 31% of patients who met the inclusion criteria² 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)

¹ See Appendix 1 for a description of standard ways for calculating total solute clearance.

² 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} ≥ 2.0 ; weekly CrCl $\geq 60\text{L/week}/1.73\text{m}^2$

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

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

| ESRD CPM Trends (percent of patients meeting the CPMs) ¹ | Year | | | | | | |
|---|------|------|------|------|------|-------------------|-----------|
| | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 ³ | 2005 |
| PD Adequacy | | | | | | | |
| PD Adequacy CPM I (measurement of total solute clearance at regular intervals) | 82 | 83 | 85 | 86 | 88 | 86 | 82 |
| PD Adequacy CPM II (weekly Kt/V _{urea} & weekly CrCl calculated in a standard way) ² | 55 | 59 | 62 | 62 | 65 | 44 | 41 |
| PD Adequacy CPM III (delivered PD dose meets K/DOQI thresholds) | | | | | | | |
| CAPD | 55 | 68 | 69 | 68 | 71 | 70 | 73 |
| Cycler with daytime dwell | 58 | 65 | 62 | 70 | 66 | 65 | 59 |
| Cycler without daytime dwell | 45 | 66 | 64 | 61 | 67 | 62 | 58 |
| Anemia Management | | | | | | | |
| Anemia CPM I (mean Hgb 11-12 g/dL) | 32 | 34 | 39 | 36 | 39 | 39 | 33 |
| Anemia CPM IIa (iron stores assessed for anemic patients or patients prescribed epoetin) | 70 | 68 | 72 | 74 | 77 | 79 | 77 |
| Anemia CPM IIb (iron stores maintained at K/DOQI targets) | 72 | 70 | 75 | 76 | 81 | 83 | 82 |
| Anemia CPM III (administration of IV iron to anemic patients) | 17 | 18 | 23 | 31 | 32 | 29 | 31 |

¹ See Appendix 1 for a description of the inclusion and exclusion criteria.

² See Appendix 1 for a description of standard ways for calculating total solute clearance.

³ First year for Large Dialysis Organization (LDO) electronic data submission.

NOTE: When a single year, such as 2005, 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

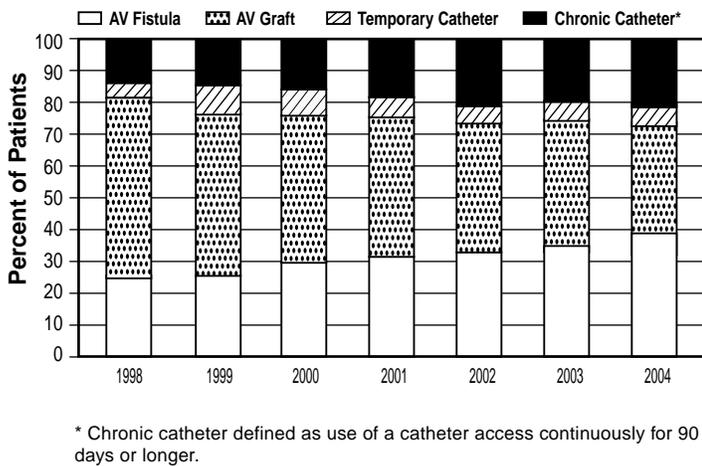
ESRD CPM Data Trends

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 2004 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 2005, 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 ≥ 18 years and "pediatric" refers to ages < 18 years.

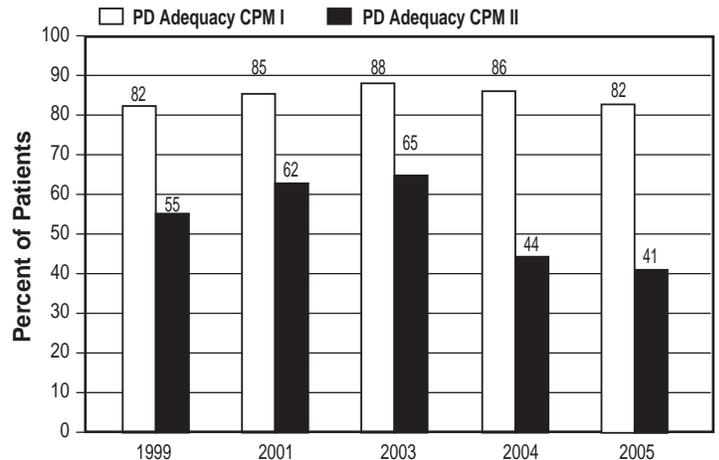
Vascular Access Trends

Figure 2: Vascular access type for all adult in-center hemodialysis patients on their last hemodialysis session during the study period. 2005 ESRD CPM Project.



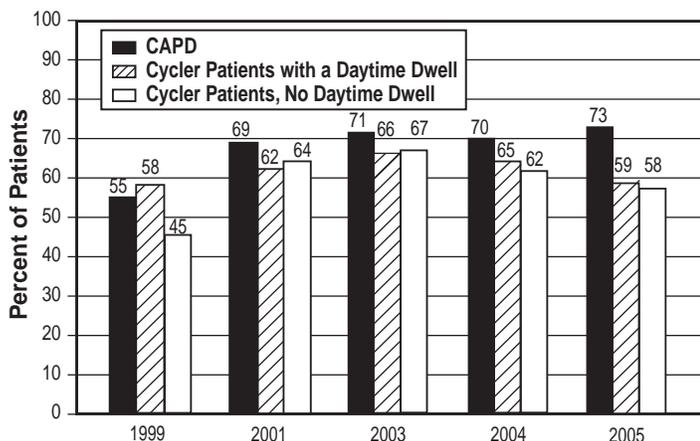
Peritoneal Dialysis Adequacy Trends

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 2004-March 2005 compared to previous study periods. 2005 ESRD CPM Project.



Peritoneal Dialysis Adequacy Trends

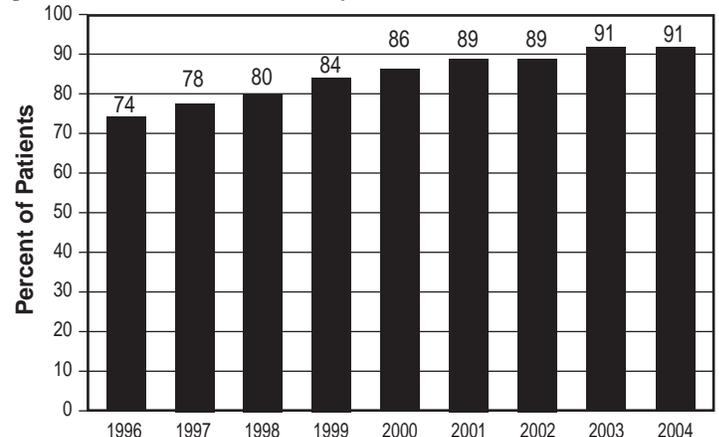
Figure 4: Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly Kt/V_{urea} and weekly creatinine clearance (PD Adequacy CPM III). 2005 ESRD CPM Project.



*See Appendix 1 for a complete description of the standard methods to calculate the solute clearance for urea and creatinine.
Note: 2004 was first year for Large Dialysis Organization (LDO) electronic data submission.

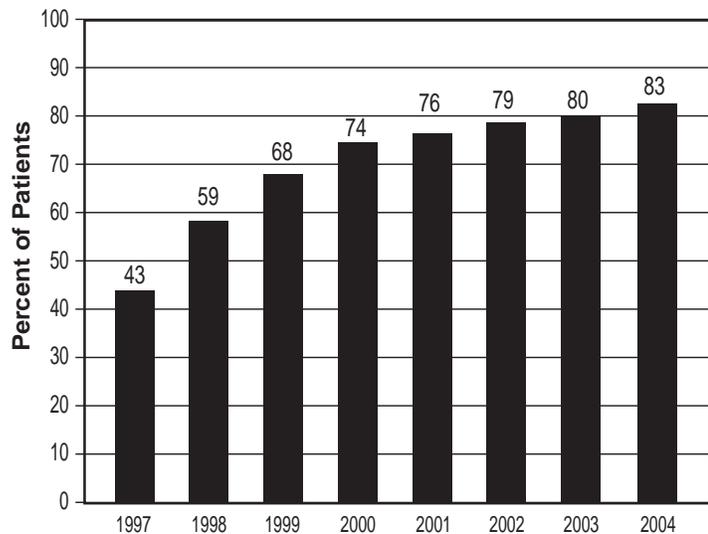
Hemodialysis Adequacy Trends

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 2004 compared to previous study periods. 2005 ESRD CPM Project.



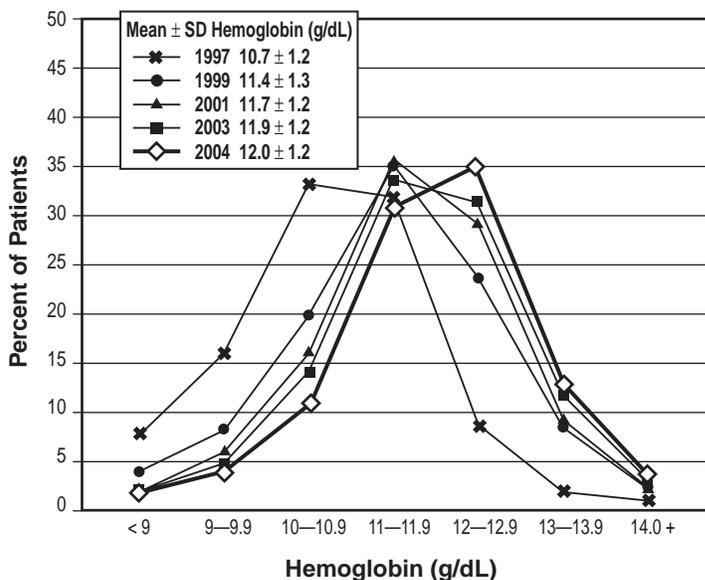
Anemia Management Trends

Figure 6: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.



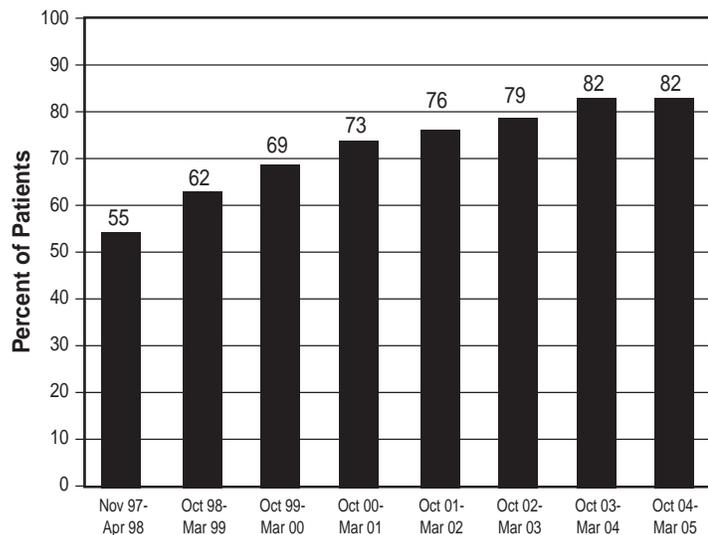
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 7: Distribution of mean hemoglobin values for adult in-center hemodialysis patients, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.



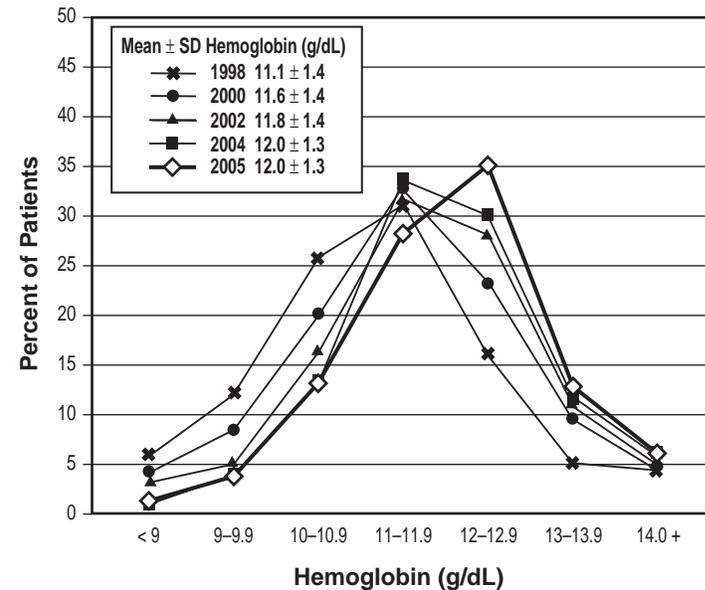
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 8: Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL, October 2004-March 2005 compared to previous study periods. 2005 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 2004-March 2005 compared to previous study periods. 2005 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 2004 compared to previous study periods. 2005 ESRD CPM Project.

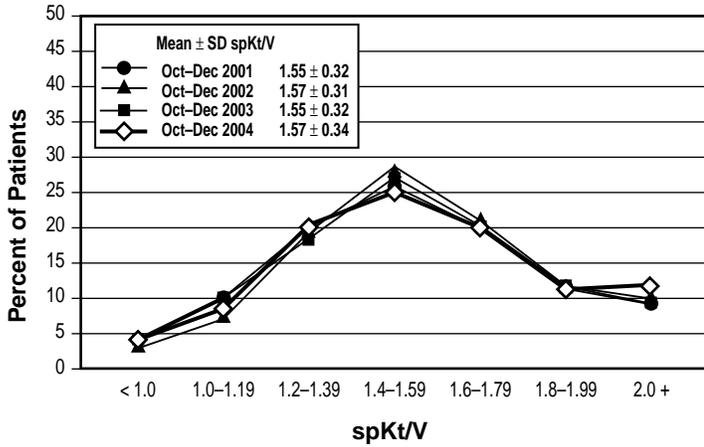
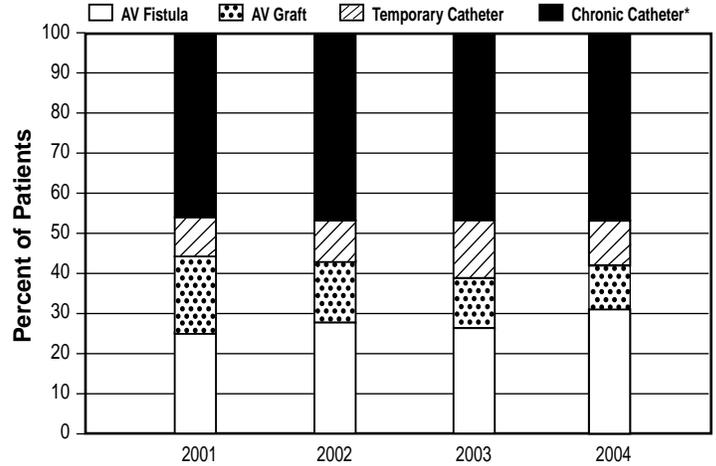
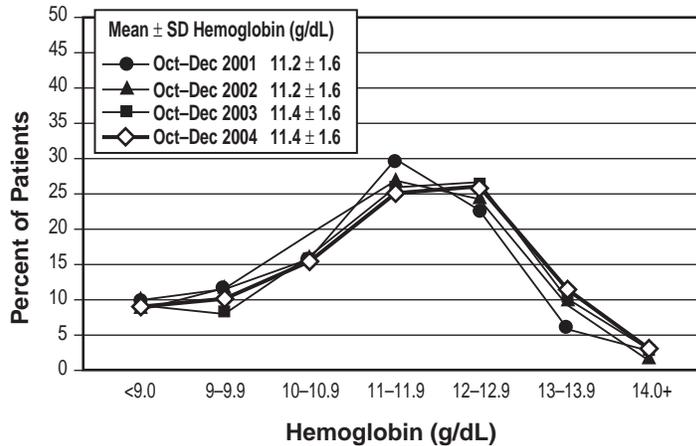


Figure 11: Vascular access type for pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period. 2005 ESRD CPM Project.



*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 2004 compared to previous study periods. 2005 ESRD CPM Project.



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

SELECTED SIGNIFICANT FINDINGS FROM THE NATIONAL 2005 ESRD CPM PROJECT**Random Sample of Adult In-Center Hemodialysis (HD) Patients (n=8,479 sample for analysis)
The data are from OCT-DEC 2004:****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 87% of male patients were receiving dialysis with a mean delivered calculated, single session $\text{spKt/V} \geq 1.2$ in OCT-DEC 2004 (TABLE 7)
- Mean \pm SD spKt/V was 1.55 ± 0.27 (FIGURE 13)
- 87% of patients had a mean URR $\geq 65\%$
- Mean \pm SD URR was $72 \pm 7\%$
- Mean \pm SD dialysis session length was 217 ± 32 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

- 37% of incident and 39% of prevalent patients were dialyzed with an AVF during their last hemodialysis session OCT-DEC 2004 (FIGURE 30, TABLE 9)
- 66% 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

- 63% of incident patients and 61% of all patients were not dialyzed with an AVF during their last hemodialysis session OCT-DEC 2004
- 33% of patients with an AVF or AV graft did not have their access routinely monitored for the presence of stenosis during the three-month study period

Anemia Management (AM)

- 83% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) in the last quarter of 2004 (FIGURE 6)
- 6% of patients had a mean hemoglobin < 10.0 g/dL (100 g/L) (TABLE 14)

- Mean \pm SD hemoglobin was 12.0 ± 1.2 g/dL (120 ± 12 g/L) (FIGURE 7, TABLE 14)
- Mean \pm SD weekly IV and SC epoetin dose was 281 ± 281 units/kg/week and 215 ± 233 units/kg/week respectively (FIGURE 38)
- 79% of patients had a mean transferrin saturation $\geq 20\%$ (FIGURE 39, TABLE 16)
- 94% of patients had a mean serum ferritin concentration ≥ 100 ng/mL (FIGURE 39, TABLE 16)
- 22% of patients had a mean serum ferritin > 800 ng/mL (FIGURE 39, TABLE 16)
- 70% of patients were prescribed IV iron during the study period (FIGURE 39, TABLE 16)
- Mean \pm SD IV iron dose was 261 ± 205 mg/month (FIGURE 36)

Opportunities to Improve Anemia Management

- 17% of patients did not have a mean hemoglobin ≥ 11 g/dL (110 g/L) during the three-month study period
- 21% of patients did not have a mean transferrin saturation $\geq 20\%$ and 6% of patients did not have a mean serum ferritin ≥ 100 ng/mL

Serum Albumin

- 36% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL ($40/37$ g/L) (BCG/BCP)¹ (FIGURE 44, TABLE 17)
- 82% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL ($35/32$ g/L) (BCG/BCP) (FIGURE 44, TABLE 17)
- Mean \pm SD serum albumin was $3.8 \pm 0.4/3.6 \pm 0.5$ g/dL ($38 \pm 4/36 \pm 5$ g/L) (BCG/BCP) (FIGURE 40)

Opportunity to Improve Serum Albumin

- 64% 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

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

SELECTED SIGNIFICANT FINDINGS FROM THE NATIONAL 2005 ESRD CPM PROJECT

Random Sample of Adult Peritoneal Dialysis (PD) Patients (n=1,337 sample for analysis) The data are from OCT 2004–MAR 2005:

PD Adequacy

- Mean weekly Kt/V_{urea} for CAPD patients was 2.29 ± 0.65
- Mean weekly Kt/V_{urea} for Cycler patients with a daytime dwell was 2.23 ± 0.61 (TABLE 21)
- Mean weekly Kt/V_{urea} for cycler patients without a daytime dwell was 2.37 ± 0.77 (TABLE 21)

Opportunities to Improve Adequacy

- The adequacy of dialysis was not assessed during the 2005 study period for 18% of the sampled peritoneal dialysis patients
- 34% of CAPD patients did not achieve an adequate weekly Kt/V_{urea} and 35% did not achieve an adequate weekly CrCl. Likewise, 43% of cycler patients with a daytime dwell did not achieve an adequate weekly Kt/V_{urea} and 51% did not achieve an adequate weekly CrCl (TABLE 21)

Anemia Management (AM)

- 82% of patients had a mean hemoglobin ≥ 11 g/dL (FIGURES 8, 50)
- 84% of patients had a mean transferrin saturation $\geq 20\%$ (FIGURE 52)
- 87% of patients had a mean serum ferritin concentration ≥ 100 ng/mL (FIGURE 52)
- Mean \pm SD hemoglobin was 12.0 ± 1.3 g/dL (120 ± 13 g/L) (FIGURES 9, 49, TABLE 22)

- The mean \pm SD SC and IV epoetin doses were 154 ± 150 and 188 ± 173 units/kg/week, respectively (FIGURE 51)
- 15% of patients had a mean serum ferritin > 800 ng/mL (FIGURE 52)

Opportunities to Improve Anemia Management

- 18% of patients did not have a mean hemoglobin ≥ 11 g/dL (110 g/L) in the 2005 study period
- 16% of patients did not have a mean transferrin saturation $\geq 20\%$ and 13% of patients did not have a mean serum ferritin ≥ 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)¹ (FIGURE 53, TABLE 23)
- 62% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) (FIGURE 53, TABLE 23)
- Mean \pm SD serum albumin was $3.6 \pm 0.5/3.4 \pm 0.6$ g/dL ($36 \pm 5/34 \pm 6$ 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
- 38% 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

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

Using the 1997 NKF-DOQI guidelines (14):

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

For cycler patients with daytime dwell (CCPD patients): weekly $Kt/V_{urea} \geq 2.1$; weekly CrCl ≥ 63 L/week/1.73m²

For nighttime cycler patients (NIPD patients) (no daytime dwell): weekly $Kt/V_{urea} \geq 2.2$; weekly CrCl ≥ 66 L/week/1.73m²

SELECTED SIGNIFICANT FINDINGS FROM THE NATIONAL 2005 ESRD CPM PROJECT**100% Sample Pediatric In-Center Hemodialysis Patients (HD) (aged < 18 years)
(n=692 sample for analysis)****The data are from OCT–DEC 2004:****Clearance**

- 89% 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 24)
- Mean \pm SD spKt/V was 1.57 ± 0.34 (FIGURES 10, 54)
- Mean \pm SD dialysis session length was 203 ± 32 minutes

Opportunity to Improve Clearance

- 11% of patients did not have a mean $\text{spKt/V} \geq 1.2$ during the three-month study period

Vascular Access

- 31% of patients were dialyzed using an AV fistula (AVF) (FIGURE 11, TABLE 25)
- 47% of patients were dialyzed with a chronic catheter continuously for 90 days or longer (FIGURE 11)
- 48% of patients with an AVF or an AV graft had their access routinely monitored for the presence of stenosis

Opportunity to Improve Vascular Access

- 52% 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 ≥ 11 g/dL (110 g/L) (FIGURES 61, 62, 63)

- Mean \pm SD hemoglobin was 11.4 ± 1.6 g/dL (114 ± 16) g/L (FIGURES 12, 60, TABLE 27)
- Mean \pm SD weekly IV epoetin dose was 364 ± 358 units/kg/week (FIGURE 65)
- 71% of patients had a mean transferrin saturation $\geq 20\%$ (FIGURE 64)
- 81% of patients had a mean serum ferritin concentration ≥ 100 ng/mL (FIGURE 64)
- 19% of patients had a mean serum ferritin > 800 ng/mL (FIGURE 64)

Opportunity to Improve Anemia Management

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

Serum Albumin

- 46% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP)¹ (FIGURE 66, TABLE 28)
- 82% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) (FIGURE 66, TABLE 28)
- Mean \pm SD serum albumin was $3.9 \pm 0.5/3.5 \pm 0.6$ g/dL ($39 \pm 5/35 \pm 6$ g/L) (BCG/BCP)

Opportunity to Improve Serum Albumin

- 54% 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

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

SELECTED SIGNIFICANT FINDINGS FROM THE NATIONAL 2005 ESRD CPM PROJECT

100% Sample Pediatric Peritoneal Dialysis Patients (PD) (aged < 18 years) (n=761 sample for analysis)

The data are from OCT 2004 – MAR 2005:

Clearance

- 72% of cycler patients with a daytime dwell had a mean weekly $Kt/V_{urea} \geq 2.1$ (TABLE 29)
- 63% of cycler patients without a daytime dwell had a mean weekly $Kt/V_{urea} \geq 2.2$ (TABLE 29)
- Mean weekly Kt/V_{urea} for cycler patients with a daytime dwell was 2.54 ± 0.75 (TABLE 29)
- Mean weekly Kt/V_{urea} for cycler patients without a daytime dwell was 2.36 ± 0.93 (TABLE 29)

Opportunities to Improve Clearance

- 28% of cycler patients with a daytime dwell did not have a mean weekly $Kt/V_{urea} \geq 2.1$ during the six-month study period
- 37% of cycler patients without a daytime dwell did not have a mean weekly $Kt/V_{urea} \geq 2.2$ during the six-month study period

Anemia Management

- 69% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) (TABLE 32)
- Mean \pm SD hemoglobin was 11.6 ± 1.5 g/dL (116 ± 15 g/L) (TABLE 32, FIGURES 68, 69)

- Mean \pm SD SC epoetin dose was 228 ± 214 units/kg/week (FIGURE 70)
- 77% of patients had a mean transferrin saturation $\geq 20\%$
- 75% of patients had a mean serum ferritin concentration ≥ 100 ng/mL

Opportunity to improve Anemia Management

- 31% of patients did not have a mean hemoglobin ≥ 11 g/dL (110 g/L) during the six-month study period

Serum Albumin

- 33% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) (TABLE 33)
- 69% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) (TABLE 33)
- Mean serum albumin was $3.7 \pm 0.6/3.4 \pm 0.6$ g/dL ($37 \pm 6/34 \pm 6$ g/L) (BCG/BCP)

Opportunity to Improve Serum Albumin

- 67% of patients did not have a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) during the six-month study period

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 2004 (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 2004; and
- (3) a comparison of CPM and/or other quality indicators results or findings for October–December 2004 and previous study periods.

A national random sample of adult (≥ 18 years) in-center hemodialysis patients, stratified by Network, who were alive on December 31, 2004, was selected ($n=8,885$). 8,479 patients (95%) were included in the sample for analysis.

A. ADEQUACY OF HEMODIALYSIS

1. CPM Findings for October–December 2004

Data to assess three hemodialysis adequacy CPMs were collected in 2005. The time period from which these data were abstracted was October–December 2004. 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 2004). 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: 76% 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 ≥ 1.2 using the Daugirdas II for-

mula (26). This CPM is calculated on the subset of patients who had been on hemodialysis therapy for six months or longer and who were dialyzing three times per week ($n=6,422$).

FINDING: For the last quarter of 2004, 95% of the adult in-center hemodialysis patients who met the inclusion criteria (only those patients who had been on hemodialysis therapy for six months or longer and who were dialyzing three times per week [$n=6,422$]) had a mean delivered calculated, single session (hereafter referred to as delivered) hemodialysis dose of spKt/V ≥ 1.2 .

2. Other Hemodialysis Adequacy Findings for October–December 2004

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 0.6% ($n=48$) of patients were dialyzed more than three times per week over the study period; these patients were included in the following hemodialysis adequacy findings.

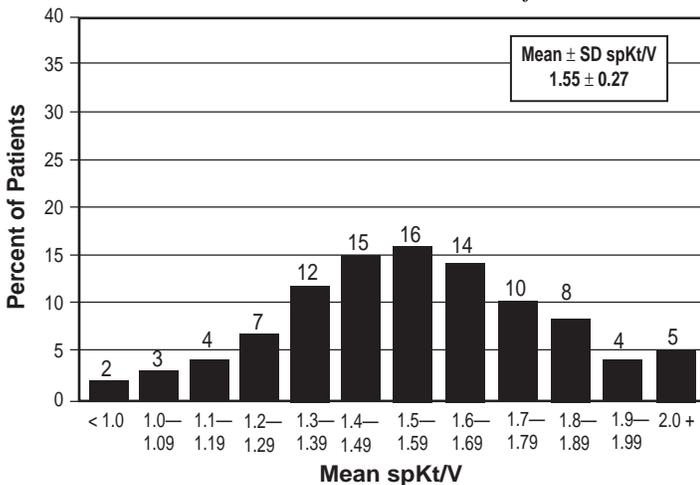
The mean \pm SD delivered calculated spKt/V of all adult in-center hemodialysis patients in the sample for analysis in the last quarter of 2004 was 1.55 ± 0.27 . The distribution of spKt/V values for these patients is shown in Figure 13. The mean \pm SD delivered calculated URR for this sample was $72 \pm 7\%$. 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 ≥ 1.2 and spKt/V ≥ 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 7.

The percent of patients in the sample for analysis with at least one calculated spKt/V measure available ($n=8,301$) who received adequate hemodialysis, defined as a mean delivered spKt/V ≥ 1.2 , approximately equivalent to URR $\geq 65\%$ (2) in the last quarter of 2003 was 91% (TABLE 7, FIGURE 5).

The percent of patients receiving hemodialysis with a mean delivered spKt/V ≥ 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 ≥ 65 years of age than for younger patients (TABLE 7).

A higher percent of patients with mean hemoglobin ≥ 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 ≥ 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 ≥ 1.2 compared to patients dialyzed with a catheter (92% and 96% vs. 82%, respectively) (TABLE 7).

Figure 13: Distribution of mean delivered calculated, single session spKt/V values for adult in-center hemodialysis patients, October–December 2004. 2005 ESRD CPM Project.



The mean \pm SD dialysis session length was 217 ± 32 minutes. The mean dialysis session length was somewhat longer for men than for women (225 minutes vs. 208 minutes), for Blacks than for Whites (223 minutes vs. 214 minutes), and for patients dialyzing six months or longer compared to patients dialyzing less than six months (217 minutes vs. 212 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. 199 minutes). The mean dialysis session length was 219 minutes for patients dialyzed with an AVF, 214 minutes for patients with an AV graft, and 217 minutes for patients with a catheter access.

Facility staff reported either the delivered blood pump flow rate (BFR) 60 minutes after the start of the dialysis session or the average delivered BFR. The mean \pm SD delivered BFR 60 minutes after the start of the dialysis session ($n=3,079$) was 401 ± 68 mL/min. The distributions of mean delivered BFR 60 minutes after the start of the dialysis session, by access type, are shown in Figure 14. The average BFR reported ($n=4,862$) was 394 ± 62 mL/min. 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).

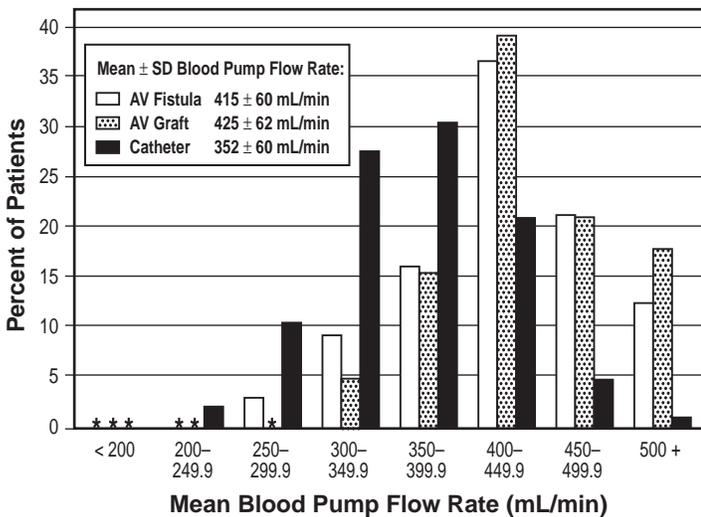
TABLE 7: Mean delivered calculated, single session spKt/V and percent of adult in-center hemodialysis patients with mean delivered calculated, single session spKt/V ≥ 1.2 and ≥ 1.3 by patient characteristics, October-December 2004. 2005 ESRD CPM Project.

| Patient Characteristics | Mean spKt/V | Percent of Patients with | |
|--|-------------|--------------------------|---------------------|
| | | spKt/V $\geq 1.2\%$ | spKt/V $\geq 1.3\%$ |
| TOTAL | 1.55 | 91 | 84 |
| GENDER | | | |
| Men | 1.48 | 87 | 79 |
| Women | 1.63 | 94 | 89 |
| RACE | | | |
| American Indian/ Alaska Native | 1.65 | 95 | 90 |
| Asian/Pacific Islander | 1.64 | 95 | 92 |
| Black | 1.52 | 89 | 81 |
| White | 1.56 | 91 | 84 |
| Other/Unknown | 1.60 | 94 | 88 |
| ETHNICITY | | | |
| Hispanic | 1.60 | 93 | 87 |
| Non-Hispanic | 1.54 | 90 | 83 |
| AGE GROUP (years) | | | |
| 18-44 | 1.51 | 88 | 80 |
| 45-54 | 1.50 | 89 | 79 |
| 55-64 | 1.53 | 89 | 81 |
| 65-74 | 1.58 | 92 | 87 |
| 75+ | 1.61 | 94 | 89 |
| CAUSE of ESRD | | | |
| Diabetes Mellitus | 1.53 | 89 | 82 |
| Hypertension | 1.56 | 91 | 85 |
| Glomerulonephritis | 1.57 | 91 | 84 |
| Other/Unknown | 1.57 | 92 | 86 |
| DURATION of DIALYSIS (years) | | | |
| < 0.5 | 1.38 | 71 | 61 |
| 0.5-0.9 | 1.49 | 88 | 78 |
| 1.0-1.9 | 1.55 | 91 | 84 |
| 2.0-2.9 | 1.58 | 94 | 88 |
| 3.0-3.9 | 1.59 | 96 | 91 |
| 4.0+ | 1.61 | 95 | 90 |
| QUINTILE POST-DIALYSIS BODY WEIGHT (kg) | | | |
| 32.0-59.4 | 1.72 | 98 | 95 |
| 59.5-68.8 | 1.60 | 94 | 89 |
| 68.9-78.6 | 1.54 | 92 | 85 |
| 78.7-92.7 | 1.49 | 89 | 80 |
| 92.8-225.6 | 1.41 | 80 | 70 |
| ACCESS TYPE | | | |
| AV Fistula | 1.56 | 92 | 86 |
| AV Graft | 1.62 | 96 | 91 |
| Catheter | 1.46 | 82 | 71 |
| MEAN Hgb (g/dL) | | | |
| ≥ 11 | 1.56 | 92 | 85 |
| < 11 | 1.50 | 84 | 76 |
| MEAN SERUM ALBUMIN (g/dL) | | | |
| $\geq 3.5/3.2$ BCG/BCP* | 1.56 | 92 | 85 |
| < 3.5/3.2 BCG/BCP | 1.50 | 85 | 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 after the start of the dialysis session for adult in-center hemodialysis patients, by access type, October–December 2004. 2005 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 < 11.

The percent of patients who received adequate hemodialysis varied significantly from one geographic region to another. Table 8 shows, by gender, race, ethnicity, post-dialysis body weight, dialysis session length, dialyzer KoA, and blood flow rate 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 86% to 94% 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 2004. 2005 ESRD CPM Project.

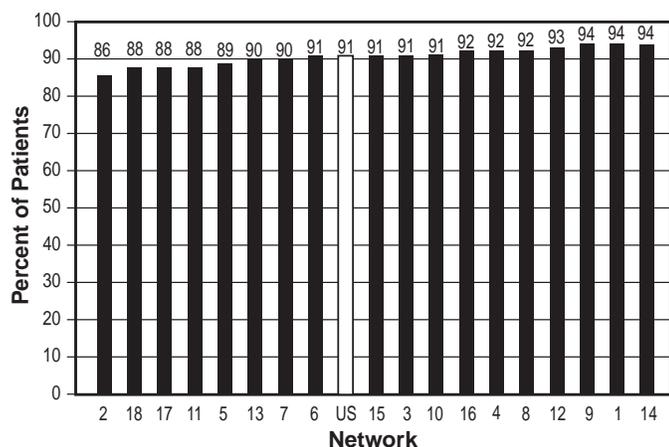
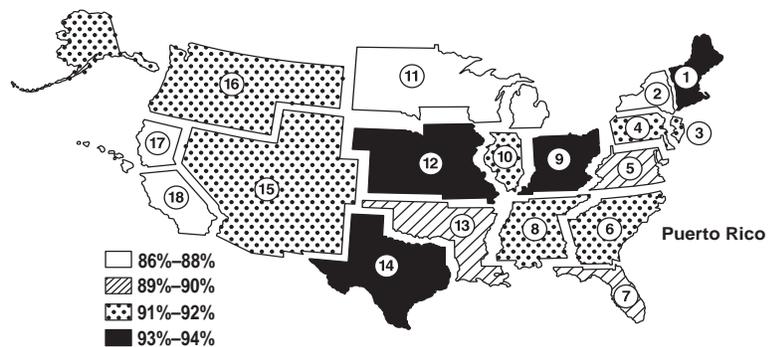


Figure 16: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V ≥ 1.2, by Network, October–December 2004. 2005 ESRD CPM Project.



3. CPM and other Findings for October-December 2004 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 2004 was 1.55 ± 0.27, 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). 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 2004 compared to previous study periods. 2005 ESRD CPM Project.

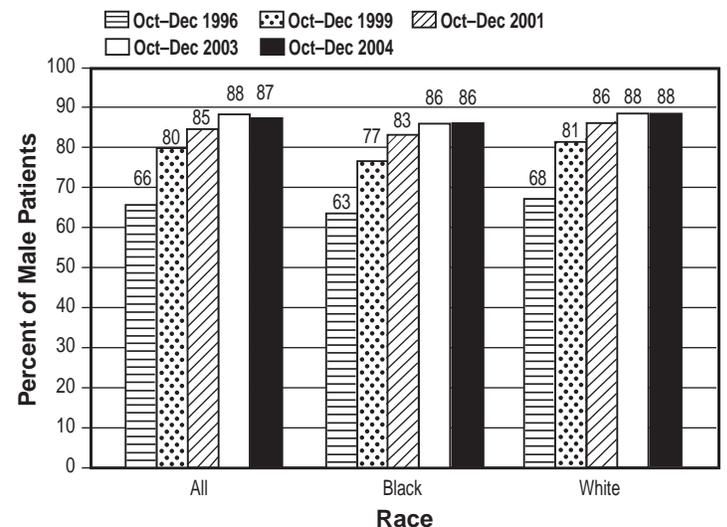


TABLE 8: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session $spKt/V \geq 1.2$, by gender, race, ethnicity, body weight, dialysis session length, dialyzer KoA, blood flow rate, and Network, October-December 2004. 2005 ESRD CPM Project.

| PATIENT CHARACTERISTIC | NETWORK | | | | | | | | | | | | | | | | | | |
|------------------------|---------|----|----|-----|----|----|----|----|-----|----|----|----|-----|-----|----|-----|----|----|------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | U.S. |
| ALL | 94 | 86 | 91 | 92 | 89 | 91 | 90 | 92 | 94 | 91 | 88 | 93 | 90 | 94 | 91 | 92 | 88 | 88 | 91 |
| GENDER | | | | | | | | | | | | | | | | | | | |
| Men | 92 | 82 | 87 | 89 | 85 | 86 | 88 | 89 | 92 | 90 | 84 | 92 | 86 | 92 | 87 | 89 | 85 | 85 | 87 |
| Women | 96 | 93 | 96 | 96 | 94 | 96 | 92 | 96 | 96 | 92 | 94 | 95 | 93 | 97 | 95 | 95 | 92 | 91 | 94 |
| RACE | | | | | | | | | | | | | | | | | | | |
| Black | 87 | 83 | 91 | 88 | 87 | 90 | 88 | 92 | 95 | 90 | 91 | 91 | 88 | 91 | 83 | 83 | 81 | 82 | 89 |
| White | 96 | 87 | 89 | 94 | 91 | 92 | 90 | 94 | 92 | 92 | 86 | 94 | 90 | 95 | 91 | 92 | 87 | 88 | 91 |
| ETHNICITY | | | | | | | | | | | | | | | | | | | |
| Hispanic | 96 | 87 | 91 | 100 | * | * | 87 | * | 100 | 97 | * | * | 92 | 97 | 95 | 100 | 94 | 89 | 93 |
| Non-Hispanic | 93 | 86 | 91 | 92 | 89 | 90 | 90 | 92 | 93 | 91 | 88 | 93 | 90 | 92 | 90 | 91 | 87 | 89 | 90 |
| POST-DIALYSIS | | | | | | | | | | | | | | | | | | | |
| BODY WEIGHT + | | | | | | | | | | | | | | | | | | | |
| < 73.64 kg | 96 | 90 | 94 | 95 | 97 | 95 | 94 | 96 | 98 | 96 | 95 | 97 | 96 | 99 | 96 | 95 | 94 | 94 | 95 |
| ≥ 73.64 kg | 91 | 83 | 88 | 90 | 81 | 86 | 85 | 90 | 90 | 86 | 83 | 90 | 85 | 89 | 84 | 88 | 81 | 80 | 86 |
| DIALYSIS SESSION | | | | | | | | | | | | | | | | | | | |
| LENGTH + | | | | | | | | | | | | | | | | | | | |
| < 212.83 min | 92 | 85 | 91 | 91 | 90 | 91 | 89 | 89 | 93 | 86 | 88 | 93 | 88 | 95 | 89 | 89 | 88 | 88 | 89 |
| ≥ 212.83 min | 96 | 88 | 92 | 93 | 87 | 91 | 92 | 95 | 94 | 95 | 89 | 94 | 91 | 94 | 92 | 93 | 90 | 90 | 92 |
| DIALYZER KoA | | | | | | | | | | | | | | | | | | | |
| 600-800 | * | 73 | * | * | * | * | 88 | 95 | 80 | 85 | * | * | 83 | * | * | * | * | * | 86 |
| 801-1000 | 95 | 78 | 94 | 90 | 87 | 89 | 90 | 92 | 97 | 95 | 88 | 99 | 95 | 93 | 95 | 89 | 86 | 85 | 91 |
| > 1000 | 94 | 89 | 91 | 93 | 92 | 92 | 92 | 93 | 96 | 92 | 92 | 93 | 92 | 97 | 90 | 92 | 90 | 92 | 93 |
| BLOOD FLOW | | | | | | | | | | | | | | | | | | | |
| RATE + + | | | | | | | | | | | | | | | | | | | |
| < 401 mL/min | 89 | 78 | 91 | 89 | 88 | 84 | 77 | 87 | 87 | 84 | 84 | 89 | 82 | 89 | 83 | 91 | 85 | 84 | 85 |
| ≥ 401 mL/min | 94 | 98 | 97 | 96 | 92 | 95 | 95 | 98 | 97 | 92 | 87 | 98 | 100 | 100 | 98 | 94 | 98 | 95 | 96 |

+ post-dialysis body weight (kg), dialysis session length, and blood flow rate categories were created at the median value for the study period

++ blood flow rate for the subset of patients with blood flow rate reported 60 minutes after the start of the dialysis session

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

* Value suppressed because $n < 11$.

Figure 18: Percent of adult female in-center hemodialysis patients with mean delivered, single session $spKt/V \geq 1.2$, by race, October–December 2004 compared to previous study periods. 2005 ESRD CPM Project.

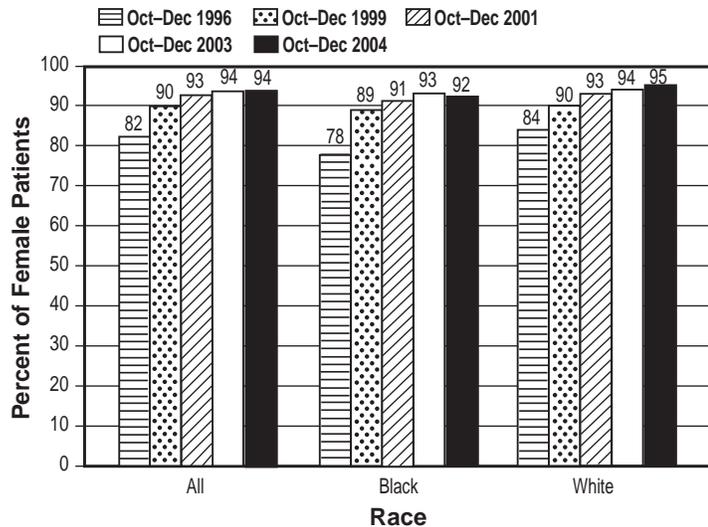
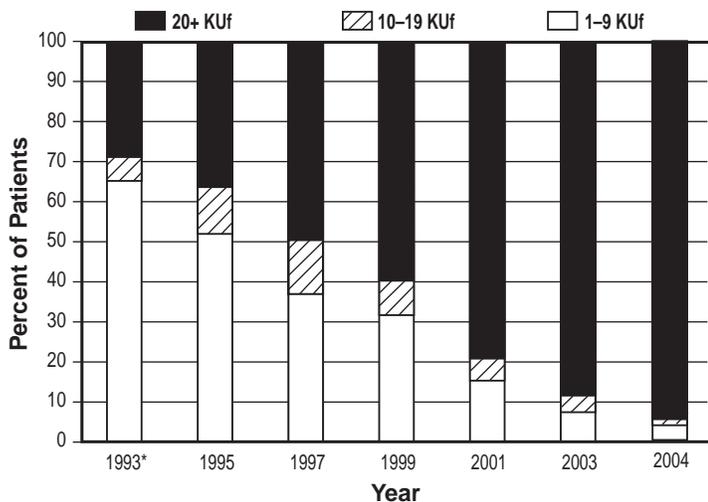


Figure 19 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category October–December 2004, compared to previous study years. The percent of patients dialyzed with a dialyzer with a KUF ≥ 20 mL/mmHg/hr increased from approximately 30% in late 1993 to approximately 94% in late 2004.

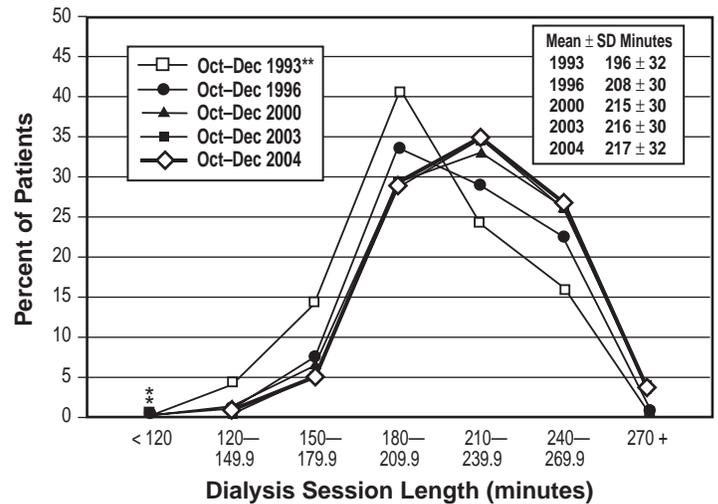
Figure 19: Percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category, October–December 2004 compared to previous study periods. 2005 ESRD CPM Project.



*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 2004.

Figure 20: Distribution of mean dialysis session length (minutes), October–December 2004 compared to previous study periods. 2005 ESRD CPM Project.



*Value suppressed because n < 11.

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

B. VASCULAR ACCESS

1. CPM Findings for October-December 2004

Data to assess three vascular access CPMs were collected in 2005. The time period from which these data were abstracted was October–December 2004. 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: 37% of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 2004 and August 31, 2004, [n = 1,342]) were dialyzed using an AVF on their last hemodialysis session during October–December 2004 (TABLE 9).

39% of all patients in the sample for analysis were dialyzed using an AVF during their last hemodialysis session October–December 2004 (TABLE 9).

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: 21% of all patients in the sample for analysis were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 2004 (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: 67% of patients with an AV graft (n=2,725) had this graft routinely monitored for the presence of stenosis during October–December 2004.

TABLE 9: Vascular access type for incident^a and all adult in-center hemodialysis patients during the last hemodialysis session of the study period, by selected patient characteristics, October-December 2004. 2005 ESRD CPM Project.

| Patient Characteristic | Incident (n=1,342) | | | Prevalent (n=8,479) | | |
|-----------------------------------|--------------------|---------|------------|---------------------|---------|------------|
| | AVF % | Graft % | Catheter % | AVF % | Graft % | Catheter % |
| TOTAL | 37 | 23 | 40 | 39 | 34 | 27 |
| GENDER | | | | | | |
| Men | 45 | 18 | 37 | 48 | 29 | 24 |
| Women | 29 | 29 | 43 | 29 | 40 | 31 |
| RACE | | | | | | |
| American Indian/ Alaska Native | * | * | * | 44 | 34 | 22 |
| Asian/Pacific Islander | 49 | 26 | 26 | 44 | 37 | 20 |
| Black | 34 | 25 | 41 | 35 | 39 | 25 |
| White | 39 | 21 | 40 | 41 | 30 | 29 |
| Other/Unknown | 27 | * | 56 | 42 | 31 | 27 |
| ETHNICITY | | | | | | |
| Hispanic | 42 | 20 | 38 | 42 | 35 | 23 |
| Non-Hispanic | 37 | 23 | 40 | 38 | 34 | 28 |
| AGE GROUP (years) | | | | | | |
| 18-44 | 55 | 11 | 35 | 50 | 24 | 26 |
| 45-54 | 31 | 30 | 39 | 40 | 35 | 25 |
| 55-64 | 42 | 21 | 37 | 38 | 36 | 27 |
| 65-74 | 37 | 25 | 38 | 36 | 37 | 26 |
| 75+ | 30 | 23 | 47 | 34 | 34 | 31 |
| CAUSE of ESRD | | | | | | |
| Diabetes Mellitus | 38 | 27 | 35 | 36 | 37 | 28 |
| Hypertension | 38 | 21 | 41 | 39 | 35 | 26 |
| Glomerulonephritis | 42 | 21 | 37 | 47 | 32 | 22 |
| Other/Unknown | 35 | 16 | 49 | 42 | 28 | 30 |
| DURATION of DIALYSIS (years) | | | | | | |
| < 0.5 | 29 | 20 | 50 | 23 | 14 | 63 |
| 0.5-0.9 | 40 | 24 | 36 | 40 | 24 | 36 |
| 1.0-1.9 | N/A | N/A | N/A | 42 | 32 | 26 |
| 2.0-2.9 | N/A | N/A | N/A | 44 | 36 | 20 |
| 3.0-3.9 | N/A | N/A | N/A | 39 | 42 | 19 |
| 4.0+ | N/A | N/A | N/A | 40 | 42 | 17 |

^aAn incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2004 and August 31, 2004.

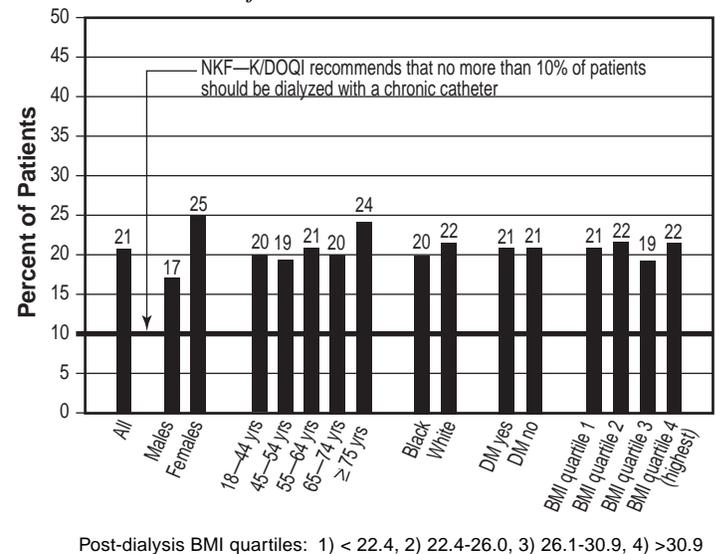
Note: Percentages may not add up to 100% due to rounding.

*Value suppressed because n < 11.

2. Other Vascular Access Findings for October-December 2004

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 2004, by patient characteristics. 2005 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 9). Many 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 9, FIGURE 22). The percent of prevalent patients with a catheter as their vascular access, by several patient characteristics, is shown in Table 9 and Figure 23. More women, Whites, and patients ≥ 75 years old, had a catheter access compared to men, Blacks, and younger patients.

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 30% to 57% among the 18 Network areas (FIGURE 24, TABLE 10). This geographic variation in AVF use was also noted for incident patients, ranging from 22% to 57% among the 18 Network areas (FIGURE 25).

The percent of patients dialyzed with a catheter exhibited geographic variation, ranging from 20% to 33% among the 18 Network areas (FIGURE 26, TABLE 11). Chronic catheter use was 21% nationally, and ranged from 15% to 31% 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 2004, by patient characteristics. 2005 ESRD CPM Project.

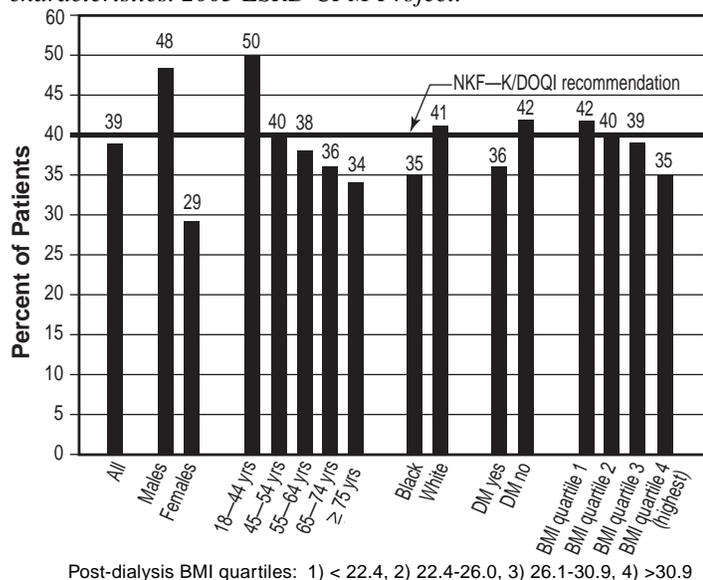


Figure 23: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October-December 2004, by patient characteristics. 2005 ESRD CPM Project.

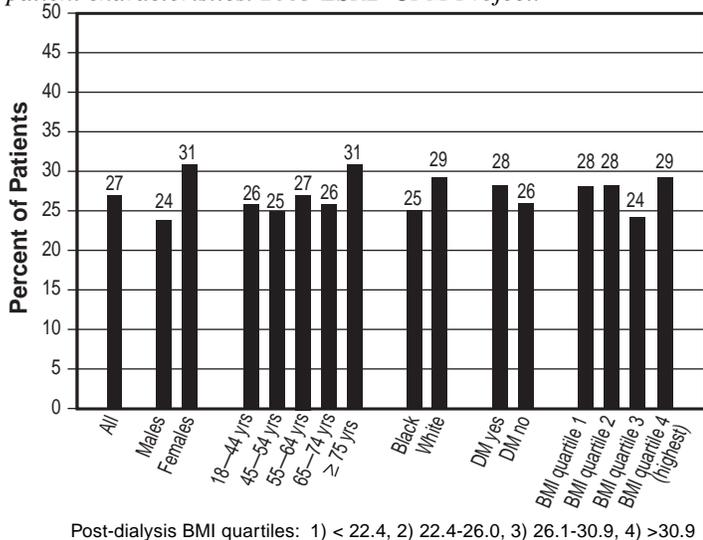


Figure 24: Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2004, by Network. 2005 ESRD CPM Project.

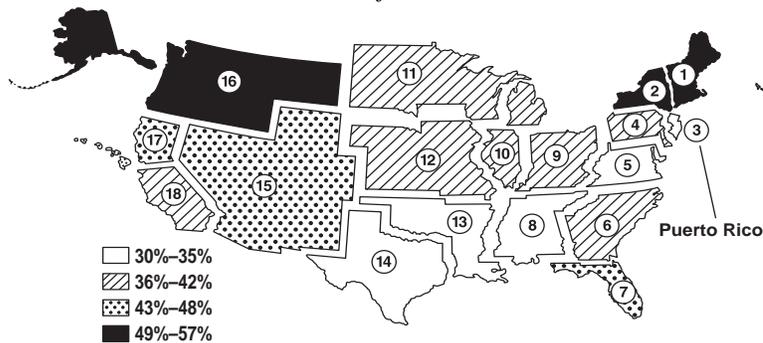
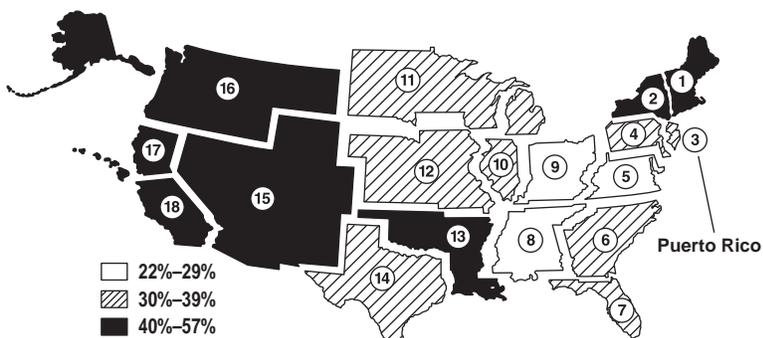


Figure 25: Percent of incident* adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2004, by Network. 2005 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2004 and August 31, 2004.

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 2004, by Network. 2005 ESRD CPM Project.

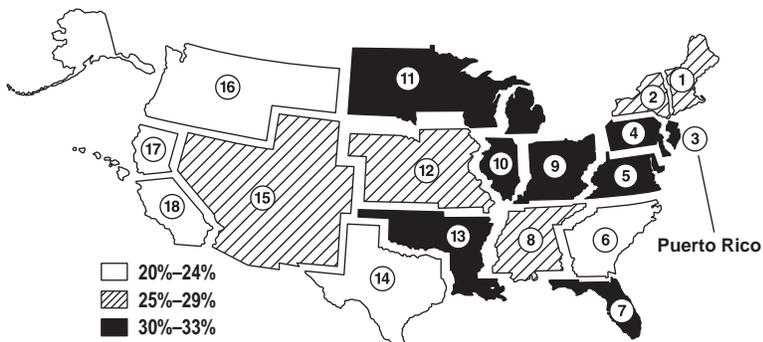


Figure 27: Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October-December 2004, by Network. 2005 ESRD CPM Project.

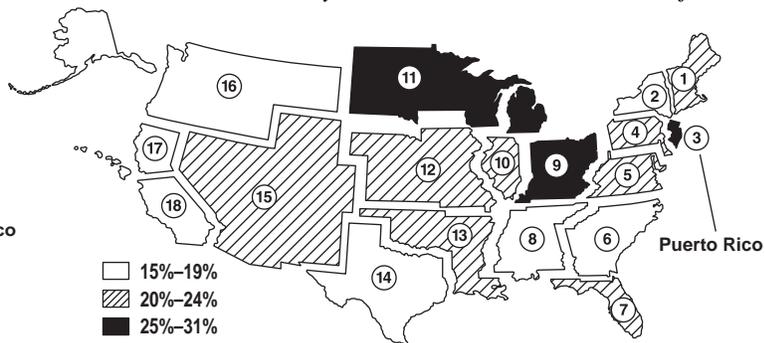


TABLE 10: Percent of all adult in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 2004, by gender, race, ethnicity, age, cause of ESRD, and Network. 2005 ESRD CPM Project.

| PATIENT CHARACTERISTIC | NETWORK | | | | | | | | | | | | | | | | | | | |
|------------------------|---------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|------|--|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | U.S. | |
| ALL | 49 | 49 | 34 | 38 | 31 | 37 | 43 | 30 | 36 | 36 | 37 | 36 | 35 | 35 | 46 | 57 | 47 | 38 | 39 | |
| GENDER | | | | | | | | | | | | | | | | | | | | |
| Men | 57 | 55 | 43 | 46 | 41 | 47 | 51 | 39 | 46 | 45 | 45 | 41 | 42 | 46 | 55 | 66 | 56 | 44 | 48 | |
| Women | 38 | 42 | 24 | 28 | 19 | 26 | 33 | 19 | 25 | 26 | 26 | 31 | 28 | 23 | 35 | 45 | 35 | 30 | 29 | |
| RACE | | | | | | | | | | | | | | | | | | | | |
| Black | 51 | 47 | 32 | 33 | 32 | 36 | 41 | 29 | 35 | 32 | 30 | 29 | 36 | 37 | 41 | 44 | 47 | 22 | 35 | |
| White | 48 | 50 | 38 | 41 | 27 | 39 | 47 | 32 | 36 | 41 | 38 | 39 | 32 | 34 | 46 | 59 | 44 | 41 | 41 | |
| ETHNICITY | | | | | | | | | | | | | | | | | | | | |
| Hispanic | 42 | 67 | 36 | * | * | * | 42 | * | * | 40 | * | * | * | 34 | 56 | 64 | 44 | 43 | 42 | |
| Non-Hispanic | 49 | 48 | 34 | 37 | 31 | 37 | 43 | 30 | 36 | 36 | 37 | 36 | 35 | 35 | 42 | 56 | 48 | 34 | 38 | |
| AGE GROUP (years) | | | | | | | | | | | | | | | | | | | | |
| 18-44 | 53 | 54 | 41 | 55 | 41 | 48 | 55 | 41 | 40 | 47 | 48 | 35 | 57 | 56 | 56 | 66 | 54 | 53 | 50 | |
| 45-54 | 58 | 52 | 32 | 47 | 31 | 36 | 35 | 33 | 47 | 33 | 35 | 38 | 39 | 34 | 44 | 50 | 53 | 47 | 40 | |
| 55-64 | 48 | 53 | 41 | 32 | 33 | 31 | 45 | 26 | 36 | 37 | 34 | 38 | 25 | 37 | 43 | 60 | 47 | 38 | 38 | |
| 65-74 | 40 | 48 | 29 | 36 | 25 | 42 | 42 | 24 | 32 | 33 | 36 | 33 | 34 | 27 | 48 | 52 | 42 | 34 | 36 | |
| 75+ | 50 | 42 | 31 | 33 | 27 | 30 | 42 | 22 | 31 | 35 | 36 | 37 | 24 | 23 | 40 | 57 | 43 | 25 | 34 | |
| CAUSE OF ESRD | | | | | | | | | | | | | | | | | | | | |
| Diabetes Mellitus | 42 | 48 | 33 | 35 | 27 | 34 | 36 | 23 | 33 | 30 | 31 | 32 | 32 | 31 | 44 | 55 | 48 | 37 | 36 | |
| Other Causes Combined | 53 | 50 | 36 | 41 | 33 | 39 | 48 | 34 | 38 | 42 | 41 | 39 | 37 | 39 | 48 | 59 | 46 | 39 | 42 | |

* Value suppressed because n < 11.

TABLE II: Percent of all adult in-center hemodialysis patients with a catheter access on their last hemodialysis session during October–December 2004, by gender, race, ethnicity, age, cause of ESRD, and Network. 2005 ESRD CPM Project.

| PATIENT CHARACTERISTIC | NETWORK | | | | | | | | | | | | | | | | | | | |
|------------------------|---------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|------|--|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | U.S. | |
| ALL | 28 | 26 | 33 | 31 | 30 | 22 | 30 | 26 | 33 | 33 | 32 | 29 | 31 | 21 | 26 | 23 | 20 | 23 | 27 | |
| GENDER | | | | | | | | | | | | | | | | | | | | |
| Men | 22 | 26 | 32 | 26 | 27 | 18 | 26 | 24 | 28 | 27 | 28 | 26 | 27 | 17 | 22 | 18 | 18 | 19 | 24 | |
| Women | 36 | 25 | 35 | 37 | 35 | 26 | 36 | 28 | 38 | 41 | 37 | 33 | 34 | 26 | 30 | 30 | 23 | 28 | 31 | |
| RACE | | | | | | | | | | | | | | | | | | | | |
| Black | 23 | 22 | 32 | 32 | 26 | 20 | 29 | 24 | 27 | 32 | 26 | 26 | 28 | 21 | 41 | 29 | 23 | 26 | 25 | |
| White | 29 | 30 | 37 | 30 | 38 | 28 | 30 | 30 | 36 | 35 | 35 | 31 | 33 | 21 | 26 | 22 | 23 | 24 | 29 | |
| ETHNICITY | | | | | | | | | | | | | | | | | | | | |
| Hispanic | * | * | 33 | * | * | * | 32 | * | * | 30 | * | * | * | 21 | 20 | * | 22 | 22 | 23 | |
| Non-Hispanic | 27 | 26 | 33 | 31 | 31 | 22 | 30 | 26 | 33 | 34 | 32 | 30 | 31 | 22 | 27 | 25 | 20 | 24 | 28 | |
| AGE GROUP (years) | | | | | | | | | | | | | | | | | | | | |
| 18-44 | 25 | 35 | 31 | 27 | 29 | 23 | 25 | 25 | 31 | 32 | * | 32 | 26 | 18 | 27 | 21 | 26 | 22 | 26 | |
| 45-54 | 25 | 19 | 32 | 24 | 32 | 18 | 34 | 20 | 29 | 33 | 28 | 29 | 22 | 24 | 32 | 27 | 21 | * | 25 | |
| 55-64 | 29 | 24 | 32 | 28 | 30 | 21 | 24 | 33 | 31 | 32 | 32 | 33 | 35 | 18 | 23 | 19 | 15 | 30 | 27 | |
| 65-74 | 30 | 22 | 36 | 37 | 29 | 19 | 28 | 22 | 34 | 34 | 33 | 28 | 35 | 23 | 21 | 26 | 23 | 18 | 26 | |
| 75+ | 28 | 33 | 35 | 34 | 33 | 31 | 38 | 33 | 38 | 36 | 38 | 26 | 33 | 24 | 26 | 24 | 17 | 27 | 31 | |
| CAUSE OF ESRD | | | | | | | | | | | | | | | | | | | | |
| Diabetes Mellitus | 30 | 25 | 31 | 32 | 29 | 21 | 34 | 27 | 33 | 35 | 32 | 34 | 32 | 26 | 26 | 24 | 19 | 24 | 28 | |
| Other Causes Combined | 27 | 27 | 35 | 29 | 31 | 23 | 27 | 25 | 32 | 31 | 32 | 25 | 30 | 17 | 25 | 22 | 21 | 22 | 26 | |

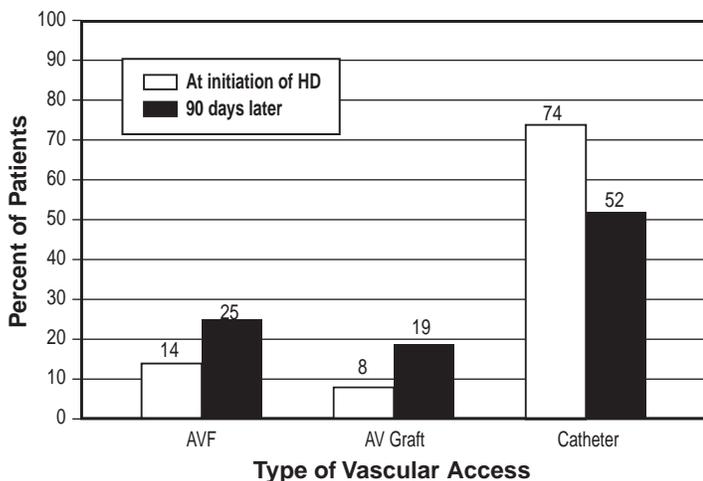
* Value suppressed because n < 11.

27% (n=2,299) of all patients in the sample for analysis were dialyzed with a catheter during their last hemodialysis session of the study period (TABLES 9, 11). The most common reasons for catheter placement were: no fistula or graft surgically planned (27%), the fistula was maturing, not ready to cannulate (21%), and no fistula or graft surgically created at this time (21%) (TABLE 12). 11% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

66% of patients with an AVF or AV graft (n=6,027) had their vascular access monitored for stenosis during the study period. For this subset of patients, 62% were monitored with dynamic venous pressure, 11% with static venous pressure, 9% with the dilution technique, 3% with Color-flow Doppler, and 26% 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). 74% 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. 2005 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2004 and August 31, 2004.

TABLE 12: Reasons for catheter placement in adult in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2004. 2005 ESRD CPM Project.

| Reason | n | (%) |
|--|--------------|--------------|
| TOTAL | 2,299 | (100) |
| No fistula or graft surgically planned | 614 | (27) |
| Patient preference | 350 | |
| Peripheral vascular disease | 140 | |
| Physician/Surgeon preference | 98 | |
| Patient size too small for AV fistula/graft | 33 | |
| Renal transplantation scheduled | 16 | |
| Fistula maturing, not ready to cannulate | 480 | (21) |
| Graft maturing, not ready to cannulate | 104 | (5) |
| No fistula or graft surgically created at this time | 475 | (21) |
| All fistula or graft sites have been exhausted | 261 | (11) |
| Temporary interruption of fistula use due to clotting or revisions | 128 | (6) |
| Temporary interruption of graft use due to clotting or revisions | 106 | (5) |
| Other | 130 | (6) |

*Note: Subtotals may not add up to 2,299 as respondents could choose multiple reasons. Percents may not add up to 100% due to rounding.

3. CPM and other Findings for October-December 2004 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 2004 compared to October-December 2003 (27% each period), more patients in 2002, 2003, and 2004 were dialyzed with a catheter compared to patients in years prior to 2002 (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 2004 and late 2003 (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 2004 (26% vs. 39%, respectively) (FIGURE 30). 26% of incident patients were dialyzed with an AVF on their last hemodialysis session in late 1998 compared to 37% in late 2004 (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 21% of all patients during October-December 2004 (FIGURE 2).

There was little change in the percent of reported surveillance techniques for patients with either an AVF or an AV graft as their vascular access from late 2000 to late 2004 (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 2004 compared to previous study periods. 2005 ESRD CPM Project.

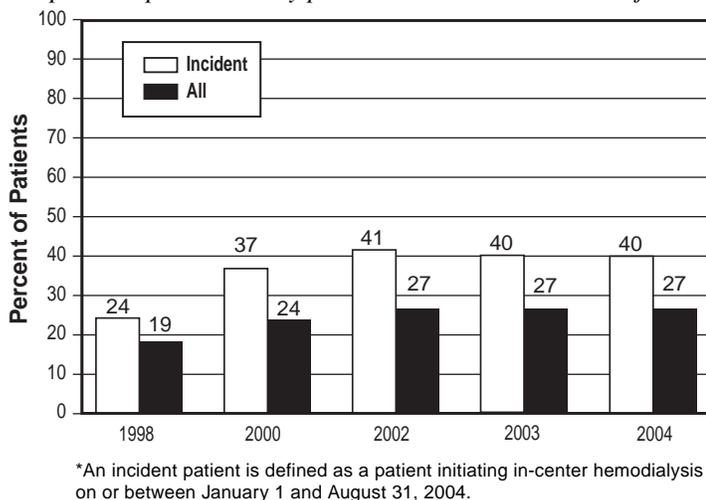


Figure 30: Percent of adult in-center hemodialysis patients (all and incident*) dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.

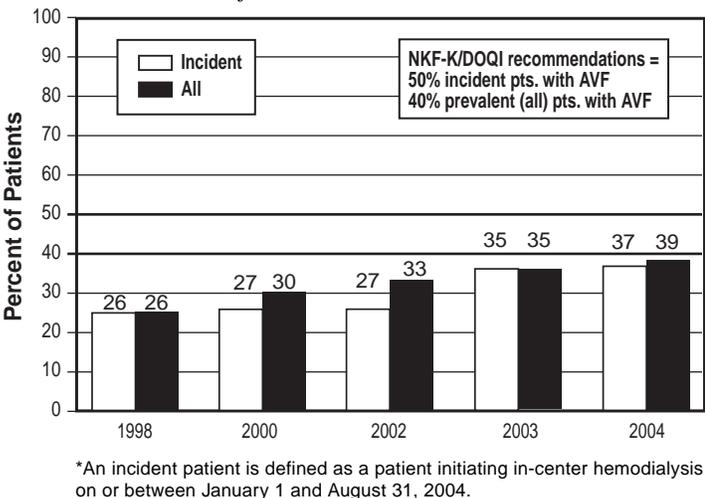
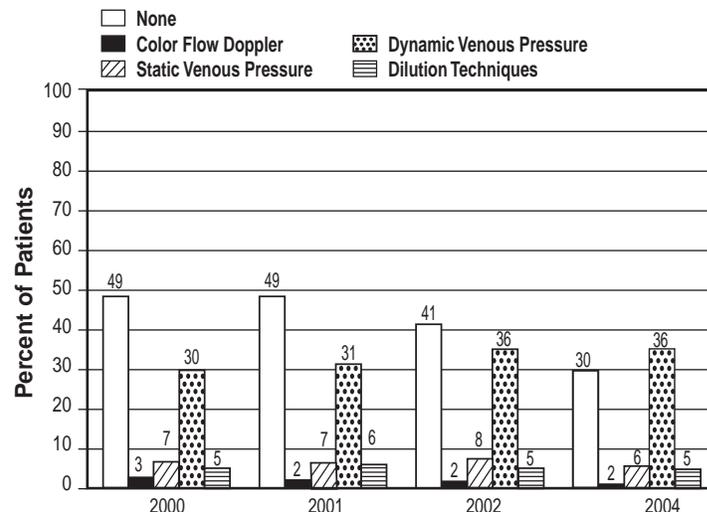


TABLE 13: Reasons for catheter placement in adult in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.

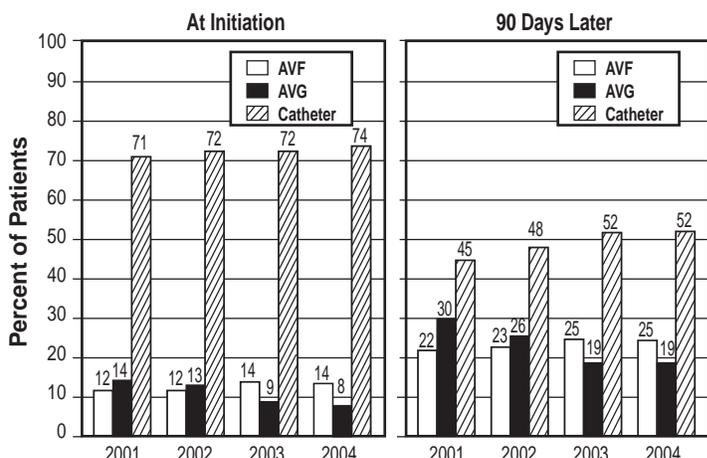
| | 2001 | 2002 | 2003 | 2004 |
|---|------|------|------|------|
| No fistula or graft surgically planned | 23 | 22 | 24 | 27 |
| Fistula or graft maturing, not ready to cannulate | 24 | 27 | 23 | 26 |
| Temporary interruption of fistula or graft due to clotting or revisions | 13 | 14 | 12 | 11 |
| No fistula or graft surgically created at this time | 20 | 18 | 22 | 21 |
| All fistula or graft sites have been exhausted | 14 | 12 | 13 | 11 |

Figure 31: Types of stenosis surveillance 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 2004 compared to previous study periods. 2005 ESRD CPM Project.



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

Figure 32: 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, late 2004 compared to previous study periods. 2005 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, 2004.

There has been a slight increase in the reason for a catheter access being "no fistula or graft surgically planned" from late 2001 to late 2004 (23% vs. 27%, respectively) (TABLE 13). There has been a trend for a slightly larger percentage of incident patients to have an AV fistula as their vascular access 90 days after initiation of a maintenance course of hemodialysis over this time period (22% vs. 25%, respectively) (FIGURE 32).

C. ANEMIA MANAGEMENT

1. CPM Findings for October–December 2004

Data were collected to assess three anemia management CPMs. The time period from which these data were abstracted was October–December 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 last quarter of 2004, 34% of the in-center hemodialysis patients who met the inclusion criteria (n=8,122) had a mean hemoglobin 11–12 g/dL (110–120 g/L).

Anemia Management CPM Iia — 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 2004, 95% of the in-center hemodialysis patients who met the inclusion criteria (n=8,049) 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 2004, 80% of the in-center hemodialysis patients who met the inclusion criteria (n=8,049) 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: 82% of the in-center hemodialysis patients who met the inclusion criteria (n=2,896) were prescribed intravenous iron in at least one month during October–December 2004.

2. Other Anemia Management Findings for October-December 2004

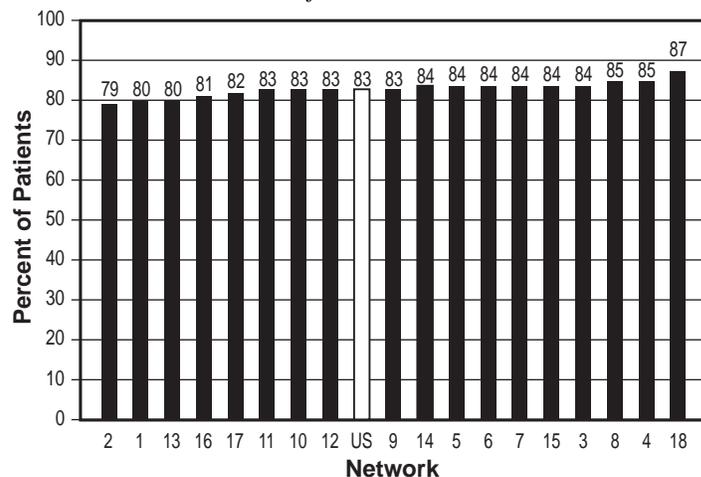
NOTE: The following findings apply to all the adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The mean ± SD hemoglobin value for all patients in this sample was 12.0 ± 1.2 g/dL (120 ±12 g/L). The mean hemoglobin values for gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters are shown in Table 14.

The mean hemoglobin value was lower for patients dialyzing less than six months compared to 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 14).

Figure 33: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by Network, October–December 2004. 2005 ESRD CPM Project.



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

TABLE 14: Mean hemoglobin values (g/dL) for adult in-center hemodialysis patients in the U.S., by patient characteristics, October–December 2004. 2005 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+ |
| TOTAL | 12.0 | 6 | 11 | 31 | 35 | 13 | 4 |
| GENDER | | | | | | | |
| Men | 12.0 | 6 | 11 | 30 | 35 | 14 | 5 |
| Women | 11.9 | 5 | 12 | 33 | 35 | 12 | 3 |
| RACE | | | | | | | |
| American Indian/ Alaska Native | 12.2 | * | * | 28 | 37 | 14 | * |
| Asian/Pacific Islander | 11.9 | 7 | 12 | 31 | 39 | 9 | * |
| Black | 12.0 | 6 | 11 | 30 | 35 | 13 | 4 |
| White | 12.0 | 5 | 11 | 32 | 35 | 13 | 4 |
| Other/Unknown | 11.9 | 7 | 14 | 30 | 33 | 10 | 6 |
| ETHNICITY | | | | | | | |
| Hispanic | 12.1 | 4 | 11 | 32 | 36 | 12 | 5 |
| Non-Hispanic | 12.0 | 6 | 11 | 31 | 35 | 13 | 4 |
| AGE GROUP (years) | | | | | | | |
| 18-44 | 12.0 | 8 | 9 | 31 | 34 | 14 | 5 |
| 45-54 | 12.0 | 8 | 13 | 28 | 32 | 14 | 5 |
| 55-64 | 12.0 | 5 | 11 | 32 | 34 | 13 | 4 |
| 65-74 | 12.0 | 5 | 12 | 32 | 37 | 12 | 3 |
| 75+ | 12.0 | 4 | 11 | 33 | 37 | 13 | 3 |
| CAUSE of ESRD | | | | | | | |
| Diabetes Mellitus | 12.0 | 5 | 11 | 32 | 35 | 12 | 4 |
| Hypertension | 12.0 | 6 | 11 | 30 | 36 | 13 | 4 |
| Glomerulonephritis | 12.0 | 5 | 8 | 33 | 36 | 12 | 5 |
| Other/Unknown | 11.9 | 7 | 12 | 30 | 33 | 15 | 4 |
| DURATION of DIALYSIS (years) | | | | | | | |
| < 0.5 | 11.5 | 17 | 18 | 25 | 23 | 13 | 3 |
| 0.5-0.9 | 12.2 | 5 | 9 | 26 | 36 | 17 | 7 |
| 1.0-1.9 | 12.0 | 3 | 11 | 33 | 36 | 13 | 3 |
| 2.0-2.9 | 12.0 | 3 | 10 | 34 | 39 | 10 | 4 |
| 3.0-3.9 | 12.0 | 4 | 12 | 35 | 35 | 12 | 2 |
| 4.0+ | 12.1 | 4 | 10 | 32 | 37 | 13 | 4 |
| MEAN spKt/V | | | | | | | |
| ≥ 1.2 | 12.0 | 5 | 11 | 32 | 36 | 13 | 4 |
| < 1.2 | 11.7 | 13 | 15 | 27 | 28 | 14 | 3 |
| MEAN SERUM ALBUMIN (g/dL) | | | | | | | |
| ≥ 3.5/3.2 BCG/BCP [^] | 12.1 | 4 | 9 | 32 | 37 | 14 | 4 |
| < 3.5/3.2 BCG/BCP | 11.5 | 14 | 21 | 29 | 25 | 9 | 2 |
| ACCESS TYPE | | | | | | | |
| AV Fistula | 12.1 | 4 | 11 | 31 | 36 | 14 | 5 |
| AV Graft | 12.1 | 3 | 10 | 34 | 37 | 12 | 4 |
| Catheter | 11.8 | 11 | 14 | 29 | 30 | 13 | 4 |

* Value suppressed because n < 11.

[^] 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.

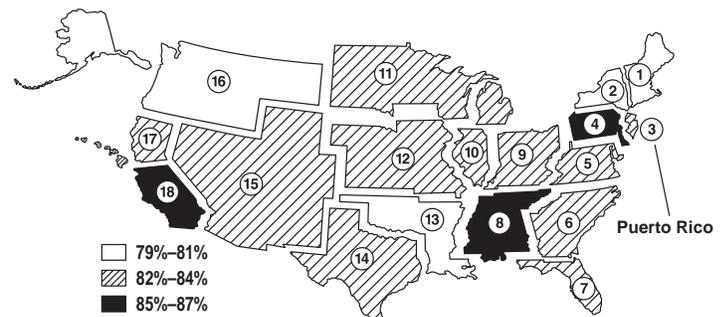
The prevalence of patients with mean hemoglobin < 10 g/dL (100g/L) was 6% nationally and ranged from 3% to 9% among Networks). The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was higher in patients dialyzing less than 6 months compared to those dialyzing 6 months or longer and higher in patients 18-54 years of age compared to older patients (TABLE 14).

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 14).

The percent of all patients with mean hemoglobin ≥ 11 g/dL (110 g/L) was 83% nationally and ranged from 79% to 87% by Network (TABLE 15, FIGURES 33, 34).

The percent of patients with mean hemoglobin ≥ 11 g/dL (110 g/L) by selected patient characteristics and clinical parameters is shown in Figure 35. 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 (86% vs. 64%, respectively). A higher percent of patients dialyzed with an AVF or an AV graft met this threshold compared to patients dialyzed with a catheter (85% and 87% compared to 76%, 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.

Figure 34: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by Network, October–December 2004. 2005 ESRD CPM Project.



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

TABLE 15: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by gender, race, ethnicity, age, access type, mean serum albumin, and Network, October-December 2004. 2005 ESRD CPM Project.

| PATIENT CHARACTERISTIC | NETWORK | | | | | | | | | | | | | | | | | | | |
|------------------------|---------|----|----|----|----|----|----|----|----|----|----|----|-----|----|----|----|----|----|------|----|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | U.S. | |
| ALL | 80 | 79 | 84 | 85 | 84 | 84 | 84 | 85 | 83 | 83 | 83 | 83 | 80 | 84 | 84 | 81 | 82 | 87 | 83 | |
| GENDER | | | | | | | | | | | | | | | | | | | | |
| Men | 80 | 79 | 82 | 84 | 85 | 84 | 86 | 88 | 82 | 83 | 81 | 85 | 80 | 84 | 84 | 82 | 85 | 88 | 84 | 84 |
| Women | 80 | 79 | 87 | 86 | 82 | 84 | 81 | 82 | 85 | 83 | 84 | 81 | 80 | 83 | 85 | 80 | 78 | 85 | 83 | 83 |
| RACE | | | | | | | | | | | | | | | | | | | | |
| Black | 79 | 79 | 85 | 83 | 84 | 82 | 86 | 83 | 81 | 78 | 84 | 83 | 81 | 85 | 73 | 83 | 78 | 91 | 82 | 84 |
| White | 81 | 80 | 86 | 88 | 84 | 87 | 82 | 89 | 85 | 86 | 81 | 83 | 81 | 83 | 85 | 82 | 84 | 87 | 84 | 84 |
| ETHNICITY | | | | | | | | | | | | | | | | | | | | |
| Hispanic | 74 | 76 | 81 | * | * | * | 89 | * | 92 | 87 | * | * | 100 | 86 | 89 | 83 | 83 | 86 | 85 | 85 |
| Non-Hispanic | 80 | 80 | 86 | 85 | 83 | 84 | 83 | 85 | 84 | 82 | 83 | 82 | 80 | 82 | 83 | 81 | 82 | 87 | 83 | 83 |
| AGE GROUP (years) | | | | | | | | | | | | | | | | | | | | |
| 18-44 | 80 | 79 | 79 | 78 | 84 | 84 | 82 | 83 | 82 | 78 | 87 | 79 | 83 | 86 | 87 | 82 | 75 | 89 | 83 | 83 |
| 45-54 | 69 | 73 | 73 | 82 | 80 | 78 | 81 | 79 | 83 | 75 | 77 | 86 | 81 | 78 | 83 | 80 | 80 | 90 | 79 | 79 |
| 55-64 | 81 | 77 | 88 | 84 | 86 | 88 | 83 | 86 | 81 | 80 | 85 | 76 | 78 | 85 | 83 | 81 | 81 | 87 | 84 | 84 |
| 65-74 | 80 | 84 | 85 | 83 | 84 | 83 | 87 | 86 | 84 | 86 | 82 | 87 | 76 | 84 | 85 | 76 | 81 | 87 | 84 | 84 |
| 75+ | 86 | 81 | 90 | 92 | 84 | 84 | 85 | 92 | 86 | 92 | 83 | 85 | 86 | 85 | 83 | 87 | 91 | 80 | 86 | 86 |
| ACCESS TYPE | | | | | | | | | | | | | | | | | | | | |
| AVF | 78 | 81 | 88 | 87 | 90 | 85 | 88 | 83 | 86 | 90 | 83 | 88 | 86 | 85 | 85 | 85 | 83 | 90 | 85 | 85 |
| AVG | 91 | 86 | 87 | 86 | 91 | 87 | 86 | 89 | 84 | 86 | 85 | 89 | 82 | 89 | 88 | 81 | 86 | 87 | 87 | 87 |
| Catheter | 77 | 68 | 78 | 82 | 70 | 76 | 77 | 79 | 80 | 73 | 79 | 69 | 71 | 71 | 79 | 75 | 73 | 80 | 76 | 76 |
| MEAN SERUM ALBUMIN | | | | | | | | | | | | | | | | | | | | |
| $\geq 3.5/3.2$ g/dL | 83 | 84 | 89 | 89 | 88 | 87 | 88 | 90 | 86 | 87 | 85 | 87 | 86 | 88 | 89 | 83 | 86 | 90 | 87 | 87 |
| BCG/BCP ^a | | | | | | | | | | | | | | | | | | | | |
| $< 3.5/3.2$ g/dL | 68 | 65 | 67 | 69 | 60 | 68 | 63 | 64 | 71 | 65 | 73 | 65 | 55 | 61 | 57 | 74 | 65 | 67 | 65 | 65 |
| BCG/BCP | | | | | | | | | | | | | | | | | | | | |

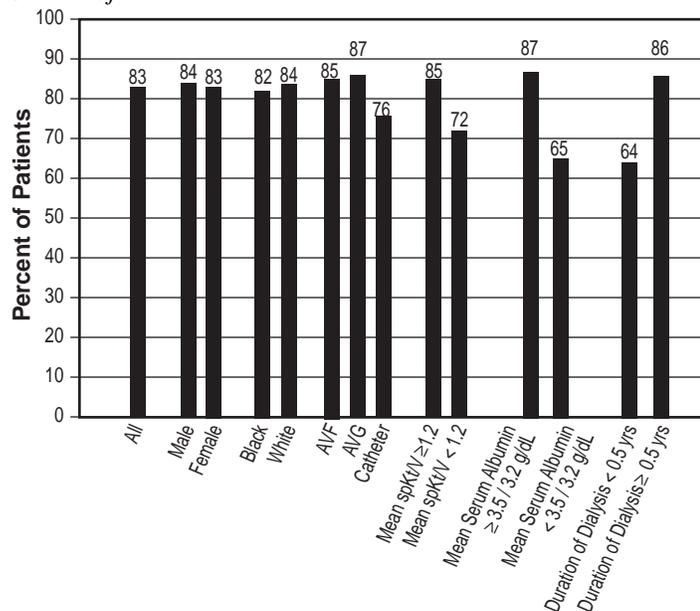
*Value suppressed because n < 11.

^a 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 35: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by selected patient characteristics and clinical parameters, October-December 2004. 2005 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 16).

The national average \pm SD transferrin saturation for the patients in the sample was $28 \pm 12\%$ and ranged from 26% to 31% among the 18 Network areas (TABLE 16). Table 16 also provides the percent of patients with mean transferrin saturation $\geq 20\%$ nationally (79%) and by Network area, ranging from 71% to 85%.

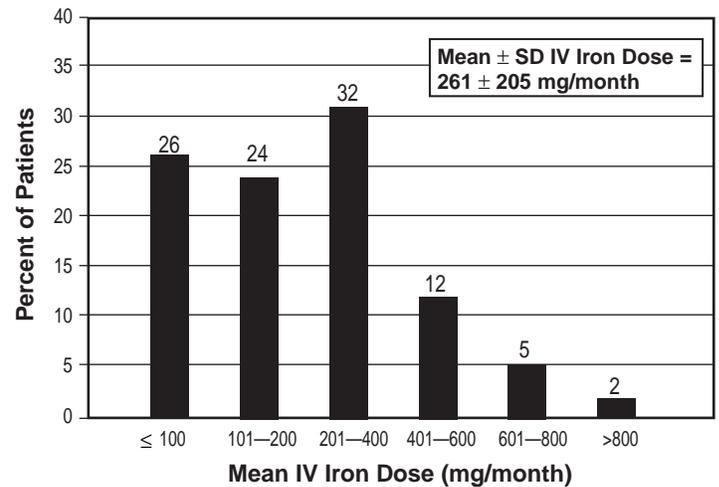
The national average \pm SD serum ferritin concentration for the patients in the sample was 576 ± 392 ng/mL and ranged from 473 to 630 ng/mL among the 18 Network areas. The percent of patients with a mean serum ferritin concentration ≥ 100 ng/mL nationally was 94%, ranging from 91% to 97% among the 18 Network areas (TABLE 16).

71% 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 70%, ranging from 63% to 75% among the 18 Network areas (TABLE 16).

For the subset of patients with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL (n=236 or 3% of patients), only 79% were prescribed IV iron at least once during the three-month study period.

The mean administered IV iron dose was 261 ± 205 mg/month. The distribution of mean administered IV iron doses (mg/month) is shown in Figure 36.

Figure 36: Distribution of mean intravenous iron doses (mg/month) for adult in-center hemodialysis patients, October-December 2004. 2005 ESRD CPM Project.



95% of all patients were prescribed ESAs. For those patients prescribed epoetin, 96% were prescribed epoetin by the IV route; and 5% 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 2% to 12% among the 18 Network areas (TABLE 16). The mean \pm SD weekly epoetin dose was 281 ± 281 units/kg/week by the IV route, and 215 ± 233 units/kg/week by the SC route.

201 (2%) patients in the sample for analysis were prescribed darbepoetin at least once during the three-month study period.

TABLE 16: Regional variation for various anemia management measures for adult in-center hemodialysis patients including the percent of patients with mean hemoglobin ≥ 11 g/dL, mean hemoglobin (g/dL), and mean serum albumin ≥ 4.0 (BCG)[^] for these patients nationally and by Network, October-December 2004. 2005 ESRD CPM Project.

| ANEMIA MANAGEMENT MEASURE: | NETWORK | | | | | | | | | | | | | | | | | | U.S. |
|--|---------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | |
| Percent of patients with mean hemoglobin ≥ 11 g/dL | 80 | 79 | 84 | 85 | 84 | 84 | 84 | 85 | 83 | 83 | 83 | 83 | 80 | 84 | 84 | 81 | 82 | 87 | 83 |
| Mean hemoglobin (g/dL) | 11.8 | 11.9 | 12.0 | 11.9 | 12.1 | 12.0 | 12.0 | 11.9 | 12.1 | 11.9 | 12.0 | 11.9 | 12.0 | 12.1 | 12.1 | 11.9 | 11.9 | 12.0 | 12.0 |
| Percent of patients with mean serum albumin ≥ 4.0 g/dL (BCG) [^] | 31 | 31 | 30 | 31 | 37 | 40 | 32 | 37 | 34 | 35 | 31 | 31 | 37 | 37 | 34 | 35 | 41 | 38 | 35 |
| Average transferrin saturation (TSAT) (%) | 26 | 30 | 27 | 27 | 29 | 28 | 29 | 27 | 28 | 27 | 28 | 27 | 28 | 29 | 29 | 28 | 27 | 31 | 28 |
| Percent of patients with mean TSAT $\geq 20\%$ | 75 | 77 | 74 | 75 | 83 | 83 | 81 | 77 | 78 | 76 | 79 | 74 | 78 | 84 | 81 | 71 | 73 | 85 | 79 |
| Average serum ferritin concentration (ng/mL) | 545 | 611 | 585 | 611 | 572 | 565 | 596 | 577 | 602 | 593 | 537 | 536 | 622 | 630 | 503 | 473 | 509 | 588 | 576 |
| Percent of patients with mean serum ferritin concentration ≥ 100 ng/mL | 91 | 93 | 95 | 92 | 93 | 95 | 93 | 95 | 97 | 95 | 93 | 95 | 96 | 95 | 93 | 94 | 93 | 93 | 94 |
| Percent of patients with mean serum ferritin concentration > 800 ng/mL | 21 | 28 | 21 | 24 | 23 | 22 | 24 | 18 | 23 | 22 | 19 | 20 | 27 | 28 | 15 | 12 | 14 | 23 | 22 |
| Percent of all patients with IV iron prescribed | 69 | 65 | 75 | 75 | 67 | 72 | 70 | 71 | 74 | 73 | 69 | 73 | 71 | 69 | 70 | 70 | 71 | 63 | 70 |
| Mean IV iron dose (mg/month) | 262 | 308 | 283 | 262 | 258 | 277 | 260 | 264 | 264 | 252 | 270 | 228 | 262 | 282 | 223 | 202 | 222 | 240 | 261 |
| Percent of patients prescribed ESA ⁺ | 98 | 94 | 96 | 93 | 95 | 96 | 95 | 94 | 95 | 96 | 92 | 94 | 95 | 94 | 96 | 93 | 95 | 94 | 95 |
| Percent of patients ⁺⁺ with subcutaneous epoetin prescribed | 2 | 3 | 12 | * | * | 3 | 3 | * | 3 | 5 | 3 | 5 | 3 | 12 | 6 | 8 | 9 | 11 | 5 |
| Percent of patients with mean hemoglobin < 11 g/dL with ESA prescribed | 98 | 94 | 96 | 90 | 94 | 94 | 93 | 92 | 96 | 89 | 96 | 93 | 97 | 91 | 95 | 94 | 94 | 89 | 94 |

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

⁺ESA – Erythropoetin Stimulating Agents

⁺⁺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.

*Value suppressed because n < 11.

3. CPM and other Findings for October-December 2004 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.

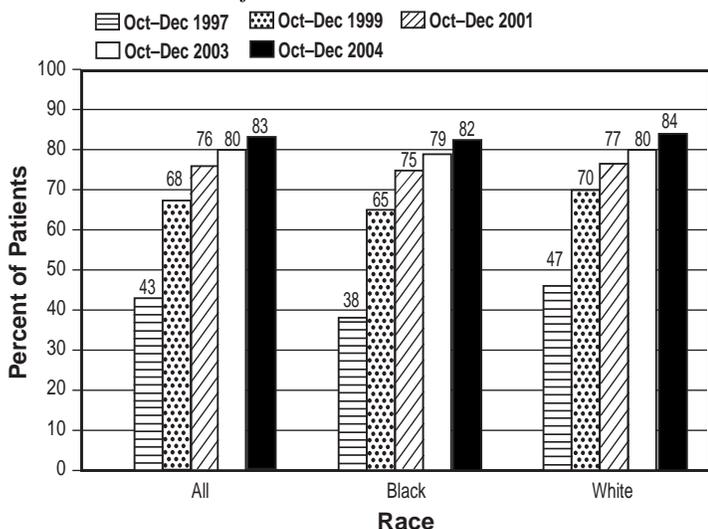
The mean \pm SD hemoglobin from October–December 2001 to October–December 2004 increased from 11.7 ± 1.2 g/dL (117 ± 12 g/L) to 12.0 ± 1.2 g/dL (120 ± 12 g/L) (FIGURE 7), and the percent of patients with a mean hemoglobin ≥ 11 g/dL (110 g/L) increased significantly from 76% to 83% (FIGURES 6, 37).

In addition to the improvement in the percent of patients with mean hemoglobin ≥ 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 2004, 6% of Black patients and 5% of White patients had a mean hemoglobin < 10 g/dL (100 g/L).

Figure 38 depicts the trend for increasing weekly epoetin dosing (units/kg/week) for selected years from late 1997 to late 2004. SC epoetin doses were systematically lower than IV epoetin doses at all hemoglobin categories examined. Of the patients prescribed epoetin, 5% of patients were prescribed SC epoetin in late 2004.

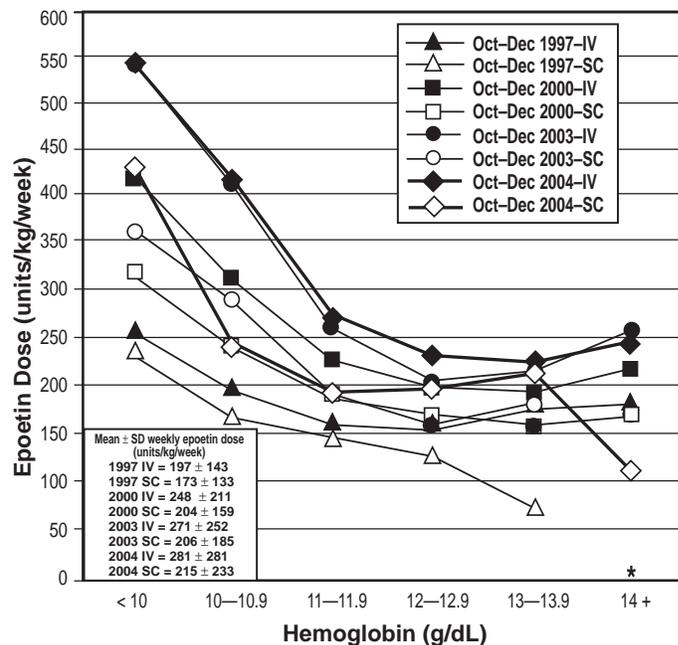
Figure 39 depicts the status of iron stores for the sampled patients in late 2004 compared to selected previous study periods. 70% of patients were prescribed IV iron in late 2004 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL, 79% of patients were prescribed IV iron at least once over the three-month study period in late 2004, compared to 37% in late 1996.

Figure 37: Percent of adult in-center hemodialysis patients with mean hemoglobin values ≥ 11 g/dL, by race, October–December 2004 compared to previous study periods. 2005 ESRD CPM Project.



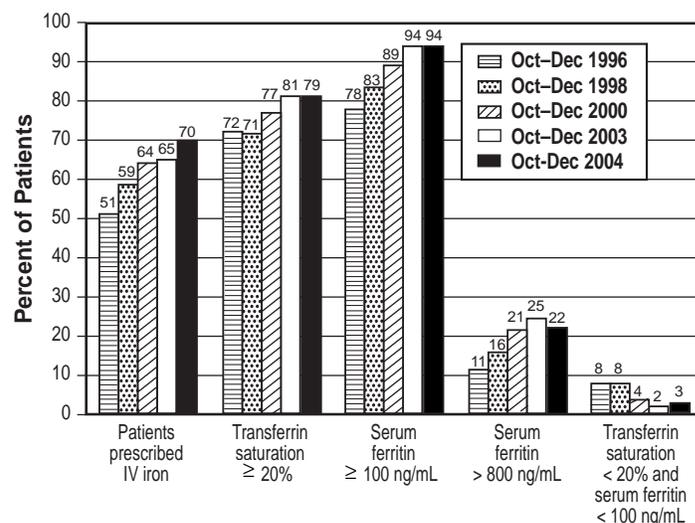
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 38: Mean prescribed weekly epoetin dose (units/kg/week) for adult in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 2004 compared to selected previous study periods. 2005 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.
*Value suppressed because n < 11.

Figure 39: Percent of adult in-center hemodialysis patients with specific anemia management indicators, October–December 2004 compared to selected previous study periods. 2005 ESRD CPM Project.



D. SERUM ALBUMIN

1. CPM Findings for October–December 2004

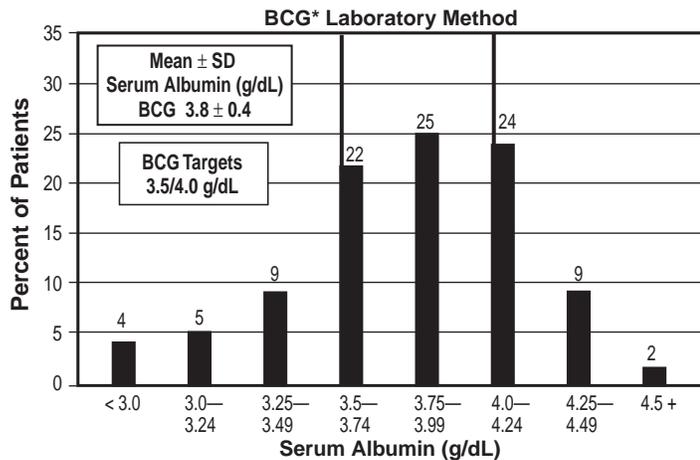
Because serum albumin is not considered to be an official CPM for this project, there are no CPM findings to report for this section.

2. Other Serum Albumin Findings for October–December 2004

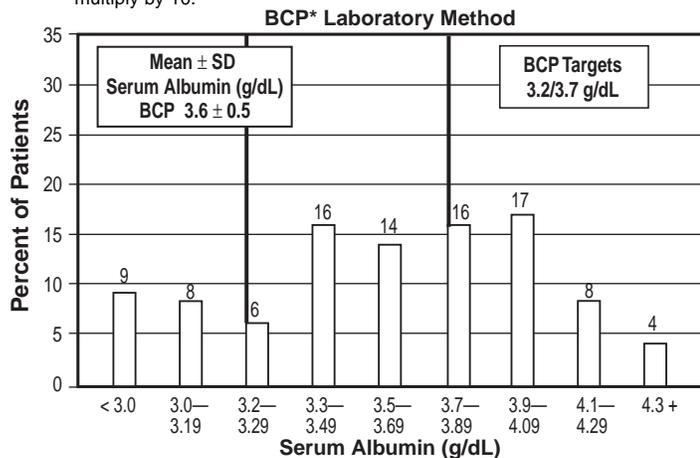
The two commonly used laboratory methods for determining serum albumin values, bromcresol green (BCG) and bromcresol purple (BCP), have been reported to yield systematically different results (6). Therefore, we assessed the serum albumin values reported for these two methods separately. The mean ± SD serum albumin value for patients whose value was determined by the BCG method (n=7,949) was 3.8 ± 0.4 g/dL (38 ± 4 g/L), and by the BCP method (n=528) was 3.6 ± 0.5 g/dL (36 ± 5 g/dL) (FIGURE 40).

Lower serum albumin values have been shown to be associated with diminished survival (29-31). Figure 40 displays the distribution of serum albumin values by laboratory method.

Figure 40: Distribution of mean serum albumin for adult in-center hemodialysis patients, by laboratory method, October–December 2004. 2005 ESRD CPM Project.



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



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

TABLE 17: Percent of adult in-center hemodialysis patients with mean serum albumin values ≥ 4.0/3.7 g/dL (BCG/BCP)* and ≥ 3.5/3.2 g/dL (BCG/BCP) in the U.S., by patient characteristics, October–December 2004. 2005 ESRD CPM Project.

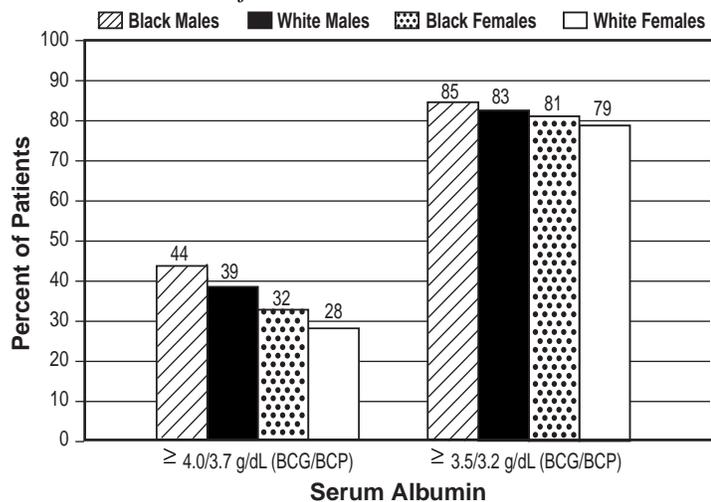
| Patient Characteristic | Percent of Patients with Mean Serum Albumin ≥ 4.0/3.7 g/dL | Percent of Patients with Mean Serum Albumin ≥ 3.5/3.2 g/dL |
|-------------------------------------|--|--|
| TOTAL | 36 | 82 |
| GENDER | | |
| Men | 41 | 84 |
| Women | 30 | 79 |
| RACE | | |
| American Indian/ Alaska Native | 26 | 77 |
| Asian/Pacific Islander | 44 | 84 |
| Black | 38 | 83 |
| White | 34 | 81 |
| Other/Unknown | 34 | 77 |
| ETHNICITY | | |
| Hispanic | 38 | 83 |
| Non-Hispanic | 35 | 81 |
| AGE GROUP (years) | | |
| 18-44 | 52 | 87 |
| 45-54 | 39 | 83 |
| 55-64 | 35 | 82 |
| 65-74 | 33 | 80 |
| 75+ | 26 | 78 |
| CAUSE of ESRD | | |
| Diabetes Mellitus | 29 | 78 |
| Hypertension | 41 | 85 |
| Glomerulonephritis | 47 | 87 |
| Other/Unknown | 39 | 82 |
| DURATION of DIALYSIS (years) | | |
| < 0.5 | 18 | 59 |
| 0.5-0.9 | 29 | 77 |
| 1.0-1.9 | 37 | 85 |
| 2.0-2.9 | 37 | 85 |
| 3.0-3.9 | 42 | 88 |
| 4.0+ | 40 | 86 |
| MEAN spKt/V | | |
| ≥ 1.2 | 37 | 83 |
| < 1.2 | 28 | 72 |
| MEAN Hgb (g/dL) | | |
| ≥ 11 | 39 | 86 |
| < 11 | 20 | 62 |
| ACCESS TYPE | | |
| AV fistula | 43 | 88 |
| AV graft | 38 | 86 |
| Catheter | 23 | 68 |

* 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.

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, duration of dialysis, and selected clinical parameters are shown in Table 17. A higher percent of men, Blacks, 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, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLES 17, 18, FIGURES 41, 42). Only 18% 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 38% of patients dialyzing six months or more.

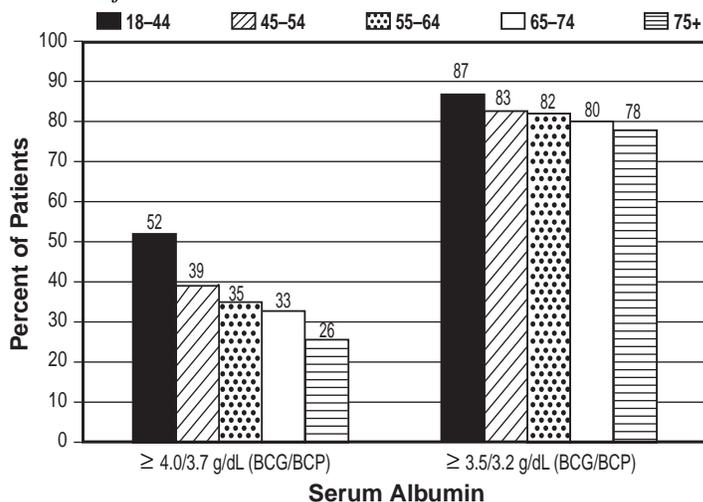
Patients with higher mean hemoglobin and mean spKt/V values had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) compared to patients with lower mean hemoglobin and mean spKt/V values. More patients dialyzed with either an AVF or an AV graft compared to patients dialyzed with a catheter had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) (43% and 38% vs. 23% respectively) (TABLES 17, 18).

Figure 41: 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 2004. 2005 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.

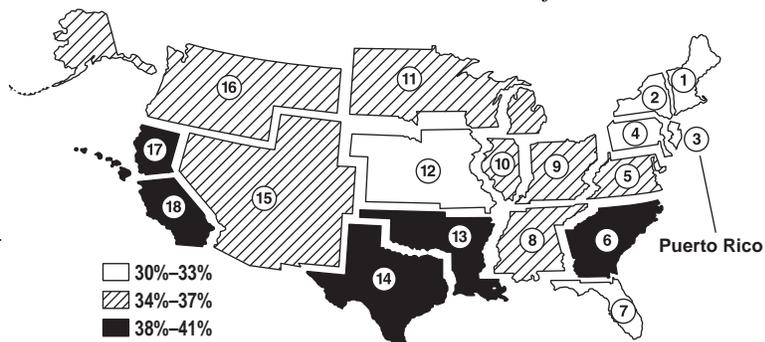
Figure 42: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP)* and $\geq 3.5/3.2$ g/dL (BCG/BCP), by age, October–December 2004. 2005 ESRD CPM Project.



* 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.

Nationally, 36% of patients had mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) ranging from 30% to 41% among the 18 Networks (FIGURE 43, TABLE 18); 82% 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 with mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP), by gender, race, ethnicity, age group, cause of ESRD, and selected clinical parameters is shown in Table 18.

Figure 43: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP)* by Network, October–December 2004. 2005 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 18: 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, access type, mean spKt/V, mean hemoglobin, and Network, October-December 2004. 2005 ESRD CPM Project.

| PATIENT CHARACTERISTIC | NETWORK | | | | | | | | | | | | | | | | | | | |
|------------------------|---------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|------|----|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | U.S. | |
| ALL | 30 | 31 | 31 | 31 | 31 | 37 | 40 | 33 | 37 | 35 | 36 | 34 | 31 | 38 | 38 | 35 | 34 | 41 | 39 | 36 |
| GENDER | | | | | | | | | | | | | | | | | | | | |
| Men | 34 | 34 | 33 | 33 | 44 | 46 | 36 | 46 | 41 | 38 | 41 | 34 | 45 | 44 | 44 | 38 | 47 | 46 | 41 | |
| Women | 26 | 28 | 30 | 28 | 28 | 32 | 30 | 27 | 28 | 33 | 26 | 28 | 32 | 31 | 25 | 30 | 34 | 32 | 30 | |
| RACE | | | | | | | | | | | | | | | | | | | | |
| Black | 35 | 31 | 32 | 31 | 41 | 41 | 29 | 39 | 38 | 40 | 40 | 42 | 39 | 44 | 34 | 37 | 40 | 36 | 38 | |
| White | 30 | 34 | 31 | 30 | 30 | 35 | 35 | 32 | 32 | 32 | 31 | 26 | 39 | 35 | 37 | 32 | 42 | 38 | 34 | |
| ETHNICITY | | | | | | | | | | | | | | | | | | | | |
| Hispanic | * | 37 | 32 | * | * | * | 43 | * | * | 51 | * | * | * | 36 | 39 | 31 | 38 | 38 | 38 | |
| Non-Hispanic | 31 | 31 | 31 | 30 | 37 | 40 | 32 | 37 | 33 | 34 | 34 | 31 | 38 | 40 | 34 | 35 | 42 | 41 | 35 | |
| AGE GROUP (years) | | | | | | | | | | | | | | | | | | | | |
| 18-44 | 53 | 56 | 46 | 47 | 61 | 55 | 47 | 55 | 44 | 48 | 52 | 52 | 50 | 50 | 46 | 53 | 48 | 62 | 52 | |
| 45-54 | 37 | 36 | 33 | 39 | 38 | 35 | 45 | 38 | 31 | 39 | 37 | 41 | 35 | 44 | 36 | 34 | 47 | 48 | 39 | |
| 55-64 | 31 | 26 | 34 | 24 | 34 | 36 | 32 | 38 | 42 | 47 | 38 | 32 | 37 | 34 | 29 | 39 | 42 | 34 | 35 | |
| 65-74 | 26 | 29 | 25 | 32 | 36 | 39 | 28 | 30 | 28 | 33 | 31 | 22 | 44 | 33 | 37 | 25 | 44 | 35 | 33 | |
| 75+ | 20 | 18 | 26 | 24 | 21 | 36 | 25 | 22 | 31 | 17 | 24 | 21 | 27 | 32 | 32 | 26 | 27 | 27 | 26 | |
| CAUSE OF ESRD | | | | | | | | | | | | | | | | | | | | |
| Diabetes Mellitus | 22 | 23 | 27 | 28 | 24 | 36 | 25 | 26 | 27 | 32 | 31 | 21 | 34 | 31 | 28 | 29 | 36 | 28 | 29 | |
| Other Causes Combined | 36 | 38 | 35 | 33 | 45 | 43 | 38 | 45 | 40 | 41 | 37 | 38 | 42 | 48 | 43 | 39 | 47 | 49 | 41 | |
| ACCESS TYPE | | | | | | | | | | | | | | | | | | | | |
| AV Fistula | 34 | 34 | 39 | 39 | 48 | 43 | 46 | 44 | 46 | 40 | 38 | 32 | 46 | 48 | 44 | 41 | 51 | 48 | 43 | |
| AV Graft | 34 | 30 | 31 | 29 | 39 | 44 | 34 | 42 | 33 | 43 | 36 | 38 | 43 | 41 | 33 | 38 | 38 | 40 | 38 | |
| Catheter | 21 | 29 | 25 | 23 | 23 | 27 | 15 | 20 | 23 | 26 | 27 | 24 | 25 | 18 | 23 | 16 | 26 | 24 | 23 | |
| MEAN spKt/V | | | | | | | | | | | | | | | | | | | | |
| ≥ 1.2 | 31 | 33 | 33 | 31 | 37 | 41 | 33 | 38 | 36 | 37 | 35 | 31 | 39 | 39 | 37 | 36 | 42 | 40 | 37 | |
| < 1.2 | * | 25 | * | 31 | 39 | 30 | 33 | * | * | 29 | 25 | * | 35 | * | * | 28 | 37 | 29 | 28 | |
| MEAN HGB | | | | | | | | | | | | | | | | | | | | |
| ≥ 11 g/dL | 32 | 34 | 34 | 33 | 41 | 44 | 36 | 41 | 36 | 40 | 37 | 34 | 41 | 42 | 38 | 38 | 45 | 43 | 39 | |
| < 11 g/dL | 23 | 22 | 17 | 19 | 14 | 19 | 17 | * | 28 | 16 | 20 | 14 | 27 | 19 | 20 | 21 | 22 | * | 20 | |

* Value suppressed because $n < 11$.

** 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.

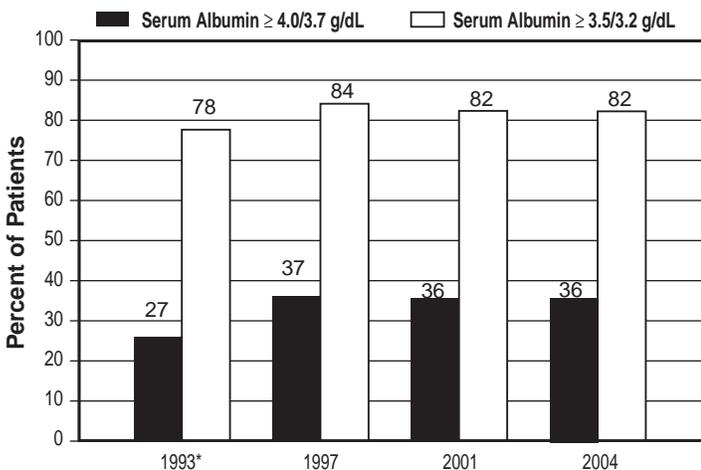
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

3. Findings for October–December 2004 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 2004 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 2004 compared to selected previous study periods.

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 2004 compared to selected previous study periods. 2005 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.

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 2004–March 2005 (the serum albumin information is not considered a CPM for this report);
- (2) a description of other quality indicators or data analyses; and
- (3) a comparison of CPM and/or other indicators or findings for October 2004–March 2005 and previous study periods.

A national random sample of adult (≥ 18 years) peritoneal dialysis patients who were alive on December 31, 2004, was selected (sample size=1,432). 1,337 patients (93%) were included in the sample for analysis.

A. ADEQUACY OF PERITONEAL DIALYSIS

1. CPM Findings for October 2004–March 2005

Data to assess three peritoneal dialysis adequacy CPMs were collected in 2005. The time period from which these data were abstracted was October 2004–March 2005. Tidal peritoneal dialysis patients (n=36) 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: 82% 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: 41% of adult peritoneal dialysis patients who had reported adequacy measurements documented in their charts 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 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For 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 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For 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 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: 73% of CAPD patients had a mean weekly Kt/V_{urea} ≥ 2.0 and a mean weekly creatinine clearance ≥ 60 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (FIGURE 4).

ALTERNATE FINDING: 77% (96/124) 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 (3) (a mean weekly Kt/V_{urea} ≥ 2.0 and for high and high-average transporters, a weekly creatinine clearance ≥ 60 L/week/1.73m², for low and low-average transporters, a weekly creatinine clearance ≥ 50 L/week/1.73m², OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period).

FINDING: 59% of cycler patients with a daytime dwell (CCPD patients) had a mean weekly Kt/V_{urea} ≥ 2.1 and a mean weekly creatinine clearance ≥ 63 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (FIGURE 4).

FINDING: 58% of cycler patients without a daytime dwell (NIPD patients) had a mean weekly Kt/V_{urea} ≥ 2.2 and a mean weekly creatinine clearance ≥ 66 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period (FIGURE 4).

2. Other Peritoneal Dialysis Adequacy Findings for October 2004-March 2005

There were 405 patients categorized as CAPD patients and 777 patients categorized as cycler patients during the study period. Tidal peritoneal dialysis patients (n=36) 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 1,063 (82%) of the 1,301 patients included for these analyses during the 2005 study period.

68% of High/High-Average transporter and 62% of Low/Low-Average transporter CAPD patients had a mean weekly Kt/V_{urea} ≥ 2.0 . 73% of High/High-Average transporter and 61% of Low/Low-Average transporter CAPD patients had a mean weekly creatinine clearance meeting NKF-K/DOQI guidelines.

57% of cycler patients with a daytime dwell had a mean calculated weekly Kt/V_{urea} and 49% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2005 study period. 60% of cycler patients without a daytime dwell had a mean calculated weekly Kt/V_{urea} and 50% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2005 study period.

23% of patients (n=295) had one or more PET results within 12 months of or during the study period. The distribution of PET results is depicted in Table 19.

45% of CAPD patients had a single prescription volume of 2,000 mL and 33% had a single prescription volume of 2,500 mL (FIGURE 45).

Distributions of 24-hour total infused dialysis solution volumes for CAPD and cycler patients are shown in Figure 46.

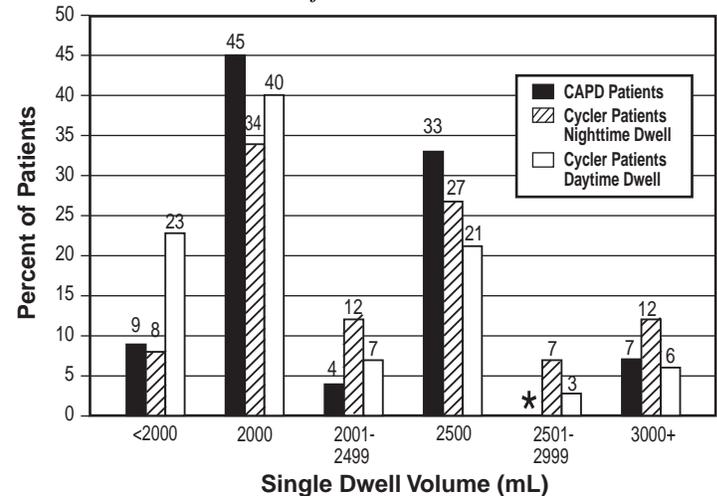
The distributions of the mean number of total exchanges for CAPD and cycler patients are shown in Figure 47. Among cycler patients, 13% (100/777) had no daytime dwell.

TABLE 19: Distribution of Peritoneal Equilibration Test (PET) results for adult peritoneal dialysis patients by modality, October 2004-March 2005. 2005 ESRD CPM Project.

| | CAPD | | Cycler Patients | |
|--------------------------|------|------|-----------------|------|
| | n | (%) | n | (%) |
| Low = 0.34-0.49 | * | (*) | 14 | (8) |
| Low-Average = 0.50-0.64 | 51 | (36) | 41 | (25) |
| High-Average = 0.65-0.81 | 66 | (47) | 88 | (53) |
| High = 0.82-1.03 | 16 | (11) | 23 | (14) |

*Value suppressed because n < 11.

Figure 45: Distribution of single dwell volumes for adult peritoneal dialysis patients, by modality, October 2004-March 2005. 2005 ESRD CPM Project.



*Value suppressed because n < 11.

Figure 46: Distribution of 24-hour total infused dialysate volumes for adult peritoneal dialysis patients, by modality, October 2004-March 2005. 2005 ESRD CPM Project.

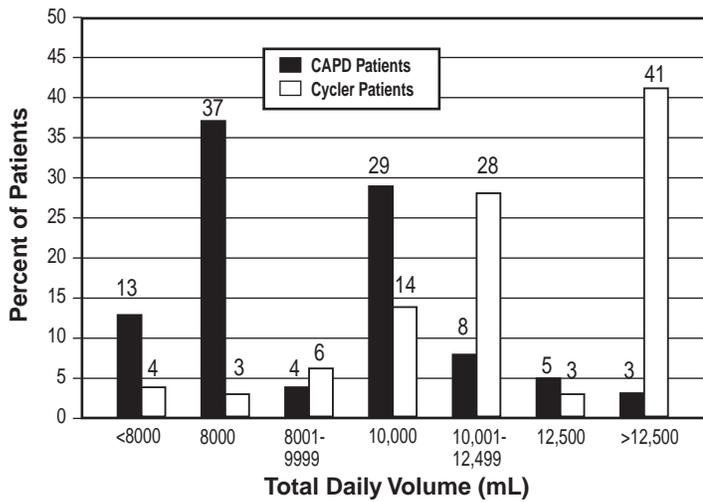
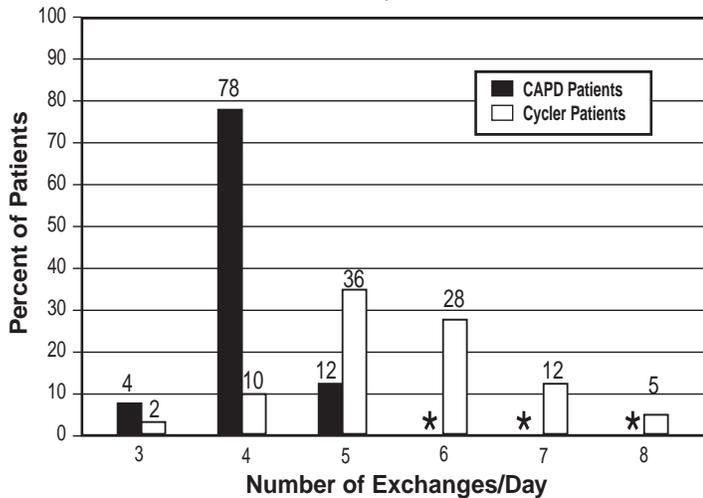


Figure 47: Distribution of the mean number of total exchanges for adult peritoneal dialysis patients, by modality, October 2004-March 2005. 2005 ESRD CPM Project.



*Value suppressed because n < 11.

3. CPM and other Findings for October 2004–March 2005 compared to previous study periods

The adequacy of peritoneal dialysis was reported for 82% of adult peritoneal dialysis patients at least once during the 2005 six-month study period, October 2004–March 2005 (PD Adequacy CPM I), compared to 86% during the 2004 study period. (FIGURE 3).

Although the percent of patients meeting NKF-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 2005 study period (FIGURES 4, 48).

Figure 48: Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly Kt/V_{urea} and weekly creatinine clearance (PD Adequacy CPM III). 2005 ESRD CPM Project.

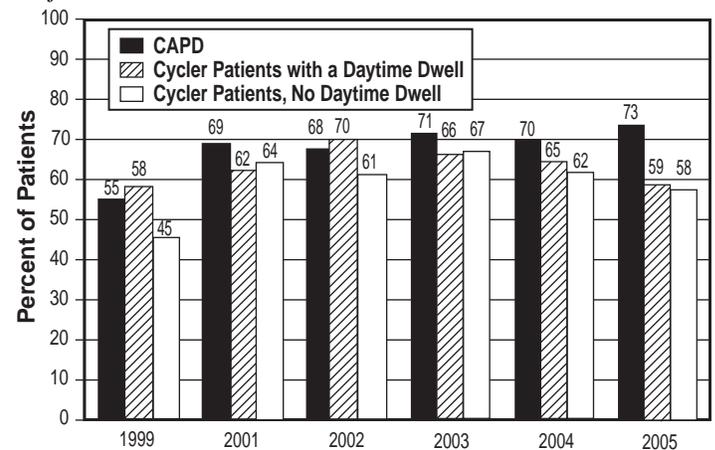


Table 20 depicts the percent of CAPD patients by transporter type with a mean calculated weekly Kt/V_{urea} and a mean calculated weekly creatinine clearance meeting recommended NKF-K/DOQI guidelines for those patients with sufficient data to calculate adequacy measures over the past five study periods.

There has been little change over the past five study periods in the percentages of cycler patients with a daytime dwell or the percentages of cycler patients without a daytime dwell meeting the NKF K/DOQI thresholds for weekly Kt/V_{urea} or weekly creatinine clearance values (TABLE 21).

TABLE 20: 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 2004–March 2005, 2005 ESRD CPM Project.

| Adequacy Measure | Oct 2000–Mar 2001 | | Oct 2001–Mar 2002 | | Oct 2002–Mar 2003 | | Oct 2003–Mar 2004 | | Oct 2004–Mar 2005 | |
|--|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|-------------------|-----------------|
| | High-Avg/High* | Low/Low-Avg | High-Avg/High | Low/Low-Avg | High-Avg/High | Low/Low-Avg | High-Avg/High | Low/Low-Avg | High-Avg/High | Low/Low-Avg |
| Weekly Kt/V_{urea} | | | | | | | | | | |
| % meeting NKF-K/DOQI [^] | 75% | 71% | 73% | 69% | 74% | 81% | 59% | 75% | 68% | 62% |
| 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 | 2.41 \pm 0.70 | 2.28 \pm 0.77 |
| median | 2.26 | 2.32 | 2.27 | 2.23 | 2.26 | 2.40 | 2.09 | 2.29 | 2.36 | 2.10 |
| Weekly Creatinine Clearance (L/week/1.73 m²) | | | | | | | | | | |
| % meeting NKF-K/DOQI | 76% | 79% | 73% | 80% | 66% | 79% | 70% | 64% | 73% | 61% |
| 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 | 81.0 \pm 27.6 | 75.4 \pm 32.2 |
| median | 78.6 | 68.5 | 72.5 | 67.6 | 72.8 | 69.6 | 74.3 | 71.3 | 76.4 | 67.8 |

[^] For CAPD patients, the delivered PD dose should be a weekly Kt/V_{urea} \geq 2.0 and a weekly creatinine clearance \geq 60 L/week/1.73m² for high-average and high transporters, and \geq 50 L/week/1.73m² 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 21: Percent of adult cycler patients with mean \pm SD weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, October 2004–March 2005, 2005 ESRD CPM Project.

| Adequacy Measure | Oct 2000–Mar 2001 | | Oct 2001–Mar 2002 | | Oct 2002–Mar 2003 | | Oct 2003–Mar 2004 | | Oct 2004–Mar 2005 | |
|---|-------------------|------------------|-------------------|------------------|-------------------|------------------|-------------------|------------------|-------------------|------------------|
| | w/daytime dwell | no daytime dwell |
| Weekly Kt/V_{urea} | | | | | | | | | | |
| % meeting NKF-K/DOQI [^] | 64% | 53% | 66% | 61% | 64% | 58% | 59% | 56% | 57% | 60% |
| 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 | 2.23 \pm 0.61 | 2.37 \pm 0.77 |
| median | 2.24 | 2.22 | 2.25 | 2.29 | 2.25 | 2.38 | 2.23 | 2.30 | 2.19 | 2.34 |
| Weekly Creatinine Clearance (L/week/1.73m²) | | | | | | | | | | |
| % meeting NKF-K/DOQI | 55% | 61% | 55% | 53% | 49% | 56% | 48% | 44% | 49% | 50% |
| 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 | 66.8 \pm 23.2 | 72.4 \pm 29.9 |
| median | 65.7 | 75.3 | 65.7 | 68.1 | 62.3 | 70.2 | 62.5 | 62.3 | 62.4 | 66.4 |

[^] For cycler patients with daytime dwell (CPD patients): Kt/V_{urea} \geq 2.1; creatinine clearance \geq 63 L/week/1.73m²
For nighttime cycler patients (no daytime dwell) (NIPD patients): Kt/V_{urea} \geq 2.2; creatinine clearance \geq 66 L/week/1.73m²

B. ANEMIA MANAGEMENT

1. CPM Findings for October 2004–March 2005

Data to assess three anemia management CPMs were collected in 2005. The time period from which these data were abstracted was October 2004–March 2005.

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, 33% of the peritoneal dialysis patients who met the inclusion criteria (n=1,188) had a mean hemoglobin 11–12 g/dL (110–120 g/L) during October 2004–March 2005.

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: 77% of the peritoneal dialysis patients who met the inclusion criteria (n=1,177) had at least two documented (measured) transferrin saturation values and at least two documented (measured) serum ferritin concentration values during October 2004–March 2005.

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 \geq 100 ng/mL and at least one transferrin saturation \geq 20% were documented during the six-month study period.

FINDING: 82% of the adult peritoneal dialysis patients who met the inclusion criteria (n=1,177) had at least one documented transferrin saturation \geq 20% and at least one documented serum ferritin concentration \geq 100 ng/mL during October 2004–March 2005.

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 \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 a trial dose of oral iron.

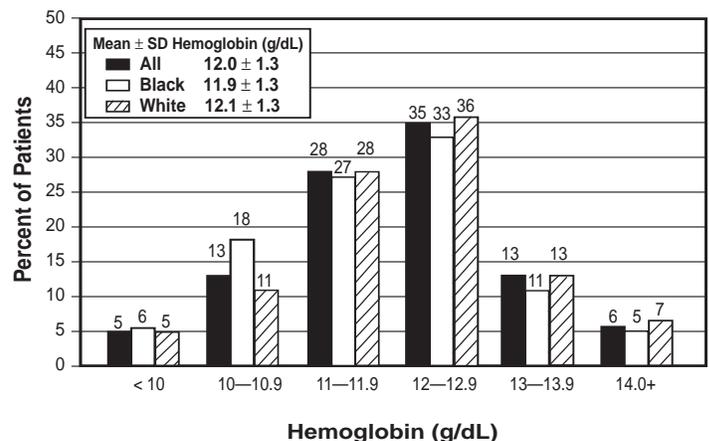
FINDING: 31% of the peritoneal dialysis patients who met the inclusion criteria (n=486) were prescribed intravenous iron at least once during October 2004–March 2005.

2. Other Anemia Management Findings for October 2004–March 2005

The mean \pm SD hemoglobin for adult peritoneal dialysis patients in the sample was 12.0 \pm 1.3 g/dL (120 \pm 13 g/L). The distributions of mean hemoglobin values for all patients and by race are depicted in Figure 49. 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 concentration and weekly creatinine clearance are shown in Table 22. Nationally, 82% of patients had a mean hemoglobin \geq 11 g/dL (110 g/L) (FIGURE 8). Significantly more Whites and patients older than 45 years had a mean hemoglobin \geq 11 g/dL (110 g/L) compared to Blacks, and younger patients (TABLE 22). A larger percentage of patients with higher mean serum albumin and weekly creatinine clearance had a mean hemoglobin \geq 11 g/dL (110 g/L) compared to patients with lower mean serum albumin and weekly creatinine clearance values. Nationally, 65% of patients prescribed ESAs 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 49, TABLE 22). The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was significantly higher in patients with lower mean serum albumin values compared to patients with higher mean serum albumin values (TABLE 22).

Figure 49: Distribution of mean hemoglobin values for adult peritoneal dialysis patients in the U.S., by race, October 2004–March 2005. 2005 ESRD CPM Project.



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

TABLE 22: Mean hemoglobin values (g/dL) for adult peritoneal dialysis patients, by patient characteristics, October 2004–March 2005. 2005 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+ |
| TOTAL | 12.0 | 5 | 13 | 28 | 35 | 13 | 6 |
| GENDER | | | | | | | |
| Men | 12.2 | 5 | 12 | 25 | 35 | 14 | 8 |
| Women | 11.9 | 6 | 15 | 31 | 35 | 11 | 3 |
| RACE | | | | | | | |
| American Indian/ Alaska Native | 12.1 | * | * | * | * | * | * |
| Asian/Pacific Islander | 12.1 | * | * | 33 | 37 | 16 | * |
| Black | 11.9 | 6 | 18 | 27 | 33 | 11 | 5 |
| White | 12.1 | 5 | 11 | 28 | 36 | 13 | 7 |
| Other/Unknown | 12.1 | * | * | 26 | 37 | * | * |
| ETHNICITY | | | | | | | |
| Hispanic | 12.1 | * | 12 | 30 | 31 | 13 | 10 |
| Non-Hispanic | 12.0 | 5 | 13 | 28 | 35 | 13 | 5 |
| AGE GROUP (years) | | | | | | | |
| 18-44 | 11.9 | 6 | 18 | 30 | 29 | 11 | 6 |
| 45-54 | 12.0 | 8 | 14 | 29 | 27 | 15 | 7 |
| 55-64 | 12.1 | * | 11 | 27 | 44 | 11 | 4 |
| 65-74 | 12.1 | * | 12 | 25 | 39 | 13 | 7 |
| 75+ | 12.2 | * | 9 | 28 | 38 | 17 | * |
| CAUSE of ESRD | | | | | | | |
| Diabetes Mellitus | 12.0 | 5 | 15 | 29 | 35 | 11 | 5 |
| Hypertension | 12.2 | 5 | 12 | 24 | 36 | 16 | 7 |
| Glomerulonephritis | 12.0 | * | 16 | 26 | 34 | 13 | 6 |
| Other/Unknown | 12.1 | 5 | 10 | 31 | 34 | 14 | 6 |
| DURATION of DIALYSIS (years) | | | | | | | |
| < 0.5 | 12.0 | 7 | 12 | 25 | 37 | 14 | 6 |
| 0.5-0.9 | 12.2 | * | 11 | 28 | 33 | 18 | 7 |
| 1.0-1.9 | 12.1 | * | 13 | 30 | 39 | 10 | 6 |
| 2.0-2.9 | 12.1 | * | 13 | 27 | 37 | 13 | * |
| 3.0-3.9 | 12.0 | * | 16 | 28 | 34 | 15 | * |
| 4.0+ | 11.9 | 9 | 15 | 28 | 31 | 10 | 7 |
| MEAN SERUM ALBUMIN (g/dL) | | | | | | | |
| ≥ 3.5/3.2 (BCG/BCP) [^] | 12.2 | 3 | 12 | 27 | 36 | 16 | 7 |
| < 3.5/3.2 (BCG/BCP) | 11.8 | 9 | 16 | 30 | 32 | 9 | 4 |
| MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m²) | | | | | | | |
| ≥60 | 12.1 | 4 | 11 | 27 | 38 | 14 | 6 |
| <60 | 11.9 | 5 | 16 | 28 | 35 | 10 | 5 |

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

[^]BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

*Value suppressed because n < 11.

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 \pm SD transferrin saturation for the patients in this sample was $30 \pm 11\%$ and 84% of patients had mean transferrin saturation $\geq 20\%$. The mean \pm SD serum ferritin concentration was 450 ± 411 ng/mL, with 87% of patients having a mean serum ferritin concentration ≥ 100 ng/mL. 15% of patients had a mean serum ferritin > 800 ng/mL. 52 patients (4% 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 ESAs during the six-month study period. ESAs were prescribed 96% of the time when the mean hemoglobin values were < 10 g/dL (100 g/L), 99% 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), 89% of the time when mean hemoglobin values were between 12-12.9 g/dL (120-129 g/L), 78% of the time when mean hemoglobin values were between 13-13.9 g/dL (130-139 g/L), and 53% 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 \pm SD weekly epoetin dose for patients prescribed epoetin by the SC route was 154 ± 150 units/kg/week; by the IV route was 188 ± 173 units/kg/week.

Iron by either the oral or IV route was prescribed at least once during the six months for 56% of the patients in this sample, and three times over the six-month period for 32% of the patients. Overall, 25% of patients were prescribed IV iron. Of the patients prescribed iron, 63% were prescribed oral iron and 44% were prescribed IV iron (not mutually exclusive categories). Among those patients with mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL ($n=52$), 77% were prescribed either oral or IV iron at least once during the six months, and 46% three times over the six-month study period.

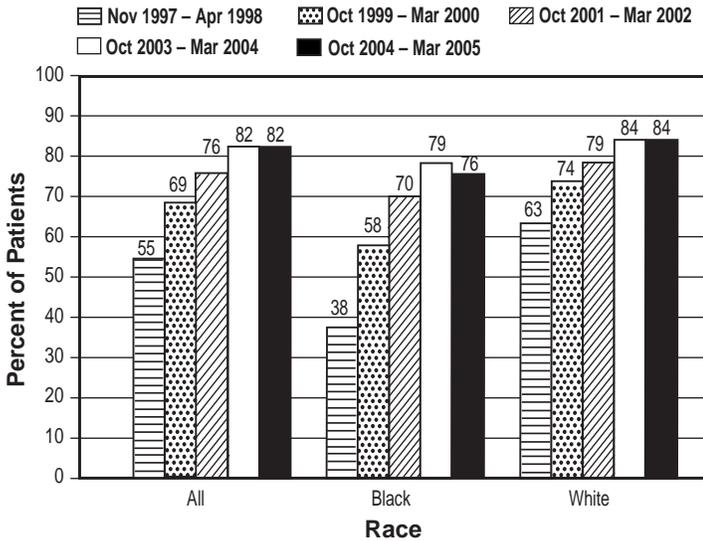
3. CPM and other Findings for October 2004–March 2005 compared to previous study periods

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 2005 study periods (FIGURE 8). This improvement was noted for both Black patients (from 38% to 76%) and for White patients (63% to 84%) (FIGURE 50). 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 2005 study period. The mean \pm SD hemoglobin increased from 11.8 ± 1.4 g/dL (118 ± 14 g/L) during the 2002 study period to 12.0 ± 1.3 g/dL (120 ± 13 g/L) during the 2005 study period (FIGURE 9). The distribution of mean hemoglobin values over this time period was not significantly different by modality (CAPD vs. Cyclus).

Figure 51 depicts the trend in epoetin dosing from the 1998 study period to the 2005 study period, with an increasing mean

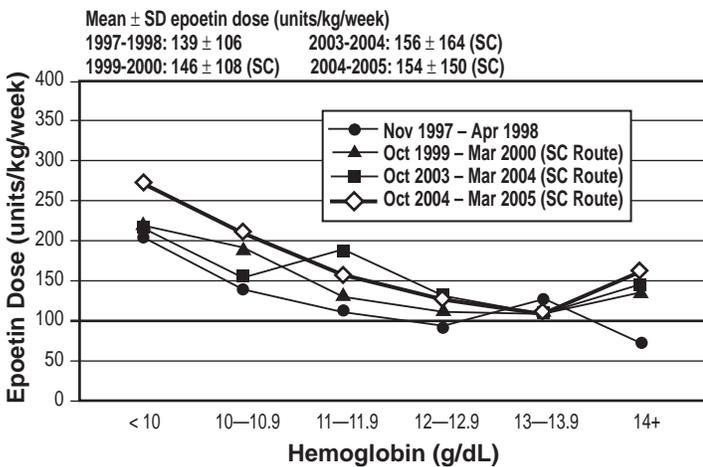
weekly epoetin dose (units/kg/week) for patients prescribed epoetin in lower hemoglobin categories. IV doses were generally larger than SC doses (data not displayed due to small cell sizes).

Figure 50: Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL, by race, October 2004–March 2005 compared to previous study periods. 2005 ESRD CPM Project.



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

Figure 51: Mean weekly epoetin dose (units/kg/week) by hemoglobin category for adult peritoneal dialysis patients prescribed epoetin, October 2004–March 2005 compared to previous study periods. 2005 ESRD CPM Project.



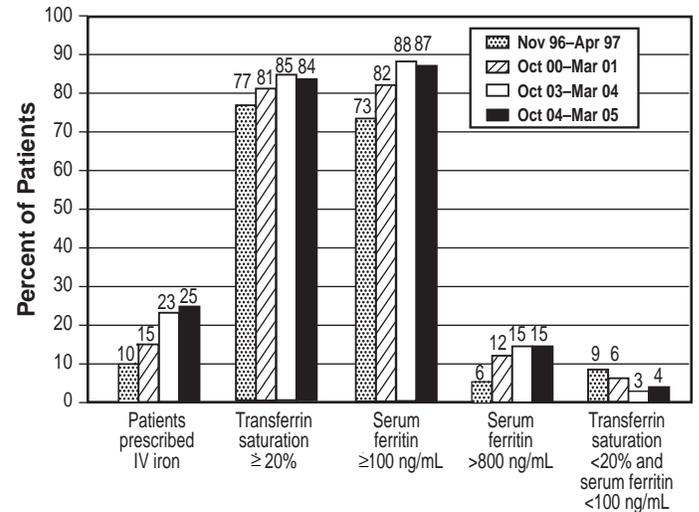
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

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 2004–March 2005 study periods.

Figure 52 depicts the status of iron stores for the sampled patients for study period 2005 compared to selected previous study periods. Overall, 25% of patients were prescribed IV iron during the 2005 study period compared to 10% during the 1997 study period. 4% of patients had a mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL during the 2005 study period compared to 9% during the 1997 study period.

Figure 52: Percent of adult peritoneal dialysis patients with specific anemia management indicators, October 2004–March 2005 compared to selected previous study periods. 2005 ESRD CPM Project.



C. SERUM ALBUMIN

1. CPM Findings for October 2004–March 2005

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 2004–March 2005

The mean \pm SD serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method (n=1,236) was 3.6 \pm 0.5 g/dL (36 \pm 5 g/L) and by the BCP method (n=100) was 3.4 \pm 0.6 g/dL (34 \pm 6 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). 62% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) by the BCG/BCP method (TABLE 23).

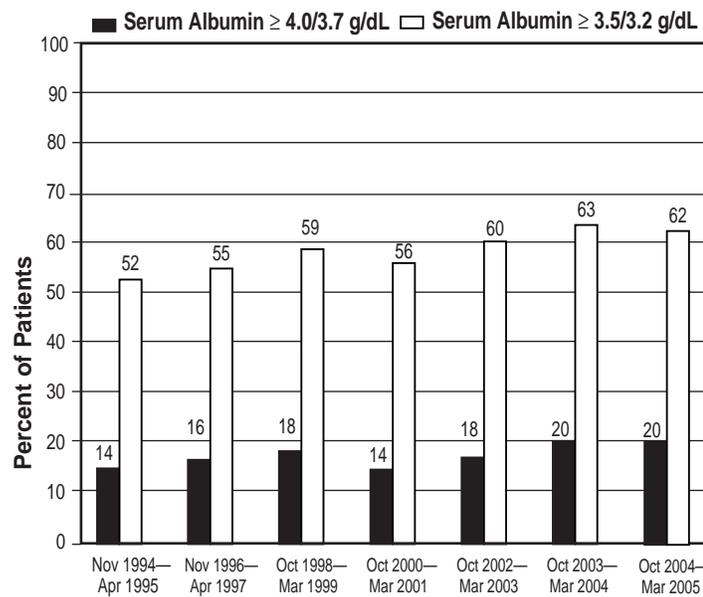
The percent of patients with mean serum albumin values $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) by gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters is shown in Table 23. The percent of patients meeting the mean serum albumin outcome goal tended to be higher for men compared to women, for patients 18-44 years compared to older patients, for patients with causes of their ESRD other than diabetes mellitus compared to patients with diabetes mellitus as the cause, and for patients with mean hemoglobin ≥ 11 g/dL compared to patients with lower hemoglobin values (TABLE 23).

3. Findings for October 2004–March 2005 compared to previous study periods

Figure 53 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 2005 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 2005 study period.

Figure 53: 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 2004–March 2005 compared to previous study periods. 2005 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 23: Percent of adult peritoneal dialysis 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 U.S., by patient characteristics, October 2004–March 2005. 2005 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 |
| TOTAL | 20 | 62 |
| GENDER | | |
| Men | 24 | 69 |
| Women | 16 | 55 |
| RACE | | |
| American Indian/ Alaska Native | * | * |
| Asian/Pacific Islander | 24 | 64 |
| Black | 22 | 61 |
| White | 19 | 63 |
| Other/Unknown | 28 | 74 |
| ETHNICITY | | |
| Hispanic | 26 | 68 |
| Non-Hispanic | 19 | 62 |
| AGE GROUP (years) | | |
| 18-44 | 33 | 71 |
| 45-54 | 22 | 63 |
| 55-64 | 19 | 63 |
| 65-74 | 10 | 54 |
| 75+ | * | 52 |
| CAUSE of ESRD | | |
| Diabetes mellitus | 9 | 49 |
| Hypertension | 28 | 73 |
| Glomerulonephritis | 28 | 69 |
| Other/Unknown | 24 | 69 |
| DURATION of DIALYSIS (years) | | |
| < 0.5 | 20 | 59 |
| 0.5-0.9 | 22 | 65 |
| 1.0-1.9 | 24 | 65 |
| 2.0-2.9 | 18 | 65 |
| 3.0-3.9 | 18 | 65 |
| 4.0+ | 18 | 58 |
| MEAN Hgb (g/dL) | | |
| ≥ 11 | 22 | 65 |
| < 11 | 10 | 49 |
| MEAN WEEKLY CREATININE CLEARANCE (L/week/1.73m²) | | |
| ≥ 60 | 21 | 64 |
| < 60 | 21 | 63 |
| MODALITY | | |
| CAPD | 18 | 60 |
| Cycler with daytime dwell | 22 | 65 |
| Cycler with no daytime dwell | 21 | 69 |

[^] BCG/BCP = bromcresol green/bromcresol purple laboratory methods.

* Value suppressed because n < 11.

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, 2004 were included in this study (n=781). 692 patients (89%) 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:

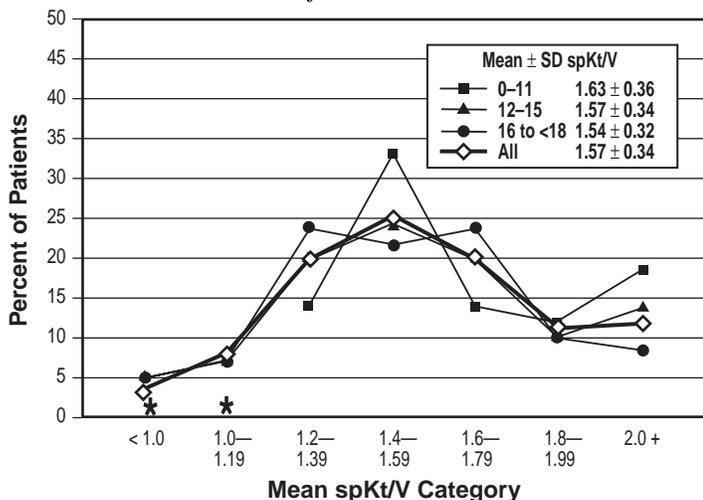
- (1) national findings for selected core indicators for October-December 2004;
- (2) a comparison of core indicator results or findings for October-December 2004 to previous study periods.

A. CLEARANCE

1. Findings for October–December 2004 (for patients < 18 years)

The percent of patients in the sample for analysis with at least one calculated spKt/V measure available (n=648) who had a mean spKt/V ≥ 1.2 in the last quarter of 2004 was 89%. The mean ± SD delivered calculated, single session spKt/V of all pediatric in-center hemodialysis patients in the sample for analysis in the last quarter of 2004 was 1.57 ± 0.34 (FIGURE 54). The distribution of spKt/V values for these patients by age is shown in Figure 54. 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 ± SD delivered calculated URR for this population was 72% ± 9%. 84% of patients had a mean delivered calculated URR ≥ 65%.

Figure 54: 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 2004. 2005 ESRD CPM Project.



*Value suppressed because n < 11.

TABLE 24: 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 ≥ 1.2, by patient characteristics, October-December 2004. 2005 ESRD CPM Project.

| Patient Characteristics | Mean spKt/V | % spKt/V ≥ 1.2 |
|--|-------------|----------------|
| TOTAL | 1.57 | 89 |
| GENDER | | |
| Males | 1.51 | 88 |
| Females | 1.65 | 90 |
| RACE | | |
| American Indian/ Alaska Native | * | * |
| Asian/Pacific Islander | 1.64 | 81 |
| Black | 1.51 | 86 |
| White | 1.60 | 91 |
| Other/Unknown | 1.61 | 88 |
| ETHNICITY | | |
| Hispanic | 1.61 | 91 |
| Non-Hispanic | 1.55 | 88 |
| AGE GROUP (years) | | |
| 0-4 | 1.67 | 86 |
| 5-9 | 1.62 | 91 |
| 10-14 | 1.57 | 90 |
| 15 to <18 | 1.55 | 88 |
| DIALYSIS SESSION LENGTH (minutes) | | |
| <180 | 1.46 | 79 |
| 180-209 | 1.51 | 88 |
| 210-239 | 1.62 | 89 |
| 240+ | 1.68 | 94 |
| DURATION of DIALYSIS (years) | | |
| < 0.5 | 1.47 | 77 |
| 0.5-0.9 | 1.49 | 87 |
| 1.0-1.9 | 1.57 | 89 |
| 2.0-2.9 | 1.63 | 98 |
| 3.0-3.9 | 1.64 | 95 |
| 4.0+ | 1.68 | 94 |
| QUINTILE POST-DIALYSIS BODY WEIGHT (kg) | | |
| 5.5-29.6 | 1.66 | 92 |
| 29.7-40.9 | 1.66 | 97 |
| 50.0-50.3 | 1.62 | 89 |
| 50.4-62.0 | 1.55 | 91 |
| 62.1-158.1 | 1.38 | 76 |
| ACCESS TYPE | | |
| AV Fistula | 1.58 | 90 |
| AV Graft | 1.67 | 96 |
| Catheter | 1.55 | 87 |
| MEAN Hgb (g/dL) | | |
| ≥ 11 | 1.56 | 89 |
| < 11 | 1.59 | 88 |
| MEAN SERUM ALBUMIN (g/dL) | | |
| ≥ 3.5/3.2 (BCG/BCP) [^] | 1.57 | 90 |
| < 3.5/3.2 (BCG/BCP) | 1.56 | 85 |

*Value suppressed because n < 11.

[^]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 ≥ 1.2 , for all patients by gender, race, ethnicity, age, dialysis session length, duration of dialysis, quintile of post-dialysis body weight, access type, and mean hemoglobin and serum albumin categories, are shown in Table 24.

A higher proportion of patients dialyzing six months or longer compared to patients dialyzing less than six months had a mean spKt/V ≥ 1.2 (92% vs. 77%), as did patients in the lowest quintile of post-dialysis body weight compared to patients in the highest quintile (92% vs. 76%), patients with dialysis sessions 240 minutes or longer compared to patients with dialysis sessions less than 180 minutes (94% 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 (90% vs. 85%).

The mean \pm SD time spent on dialysis per dialysis session was 203 ± 32 minutes. The mean time spent on dialysis was longer for males compared to females (205 minutes vs. 200 minutes), Blacks compared to Whites (208 minutes vs. 201 minutes), for patients aged 16 to < 18 years compared to patients aged 12 to 15 years and 0 to 11 years (211 minutes vs. 203 and 192 minutes, respectively), for patients dialyzing six months or longer compared to patients dialyzing less than six months (205 minutes vs. 195 minutes), for patients in the highest quintile of post-dialysis body weight compared to those patients in the lowest quintile (216 minutes vs. 190 minutes) and for patients dialyzed with an AVF compared to those patients with an AV graft or catheter access (208 minutes vs. 204 minutes and 200 minutes, respectively).

2. Findings for October-December 2004 compared to previous study periods (for patients < 18 years)

The mean \pm SD delivered spKt/V for patients aged 18 years or younger increased from 1.55 ± 0.32 in October-December 2001 to 1.57 ± 0.34 in October-December 2004. The percent of these patients receiving dialysis with a mean delivered spKt/V ≥ 1.2 increased from 87% in late 2001 to 89% in late 2004. This increase in spKt/V was specifically noted in White males and Black females (FIGURES 55, 56).

Figure 55: Percent of all pediatric (aged < 18 years) male in-center hemodialysis patients with mean delivered calculated, single session spKt/V ≥ 1.2 , by race, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.

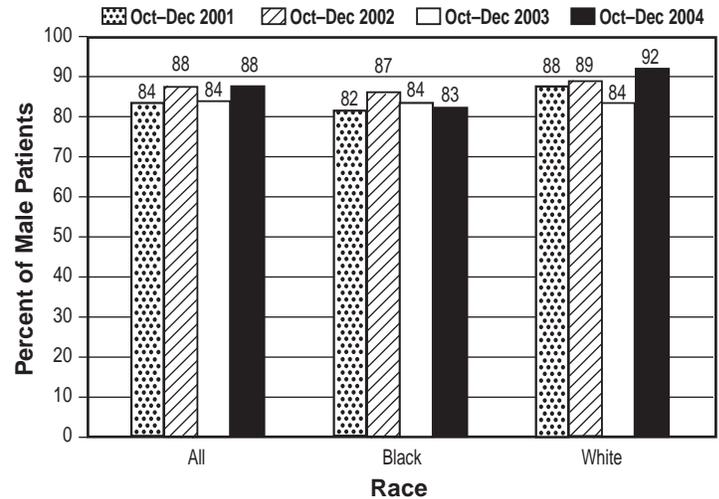
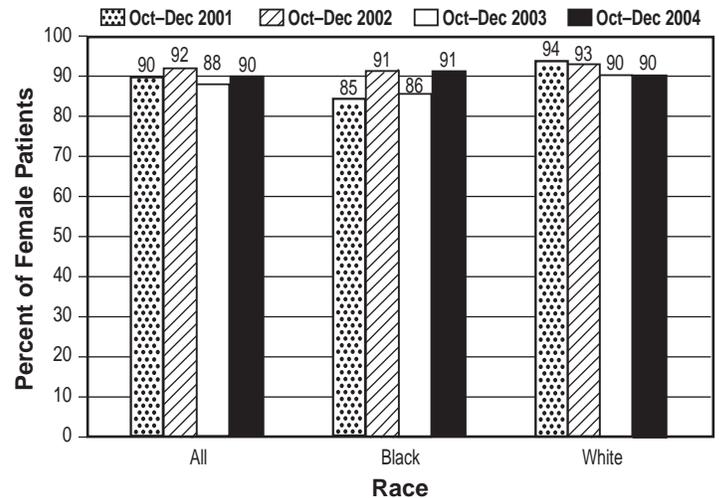


Figure 56: Percent of all pediatric (aged < 18 years) female in-center hemodialysis patients with mean delivered calculated, single session spKt/V ≥ 1.2 , by race, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.



B. VASCULAR ACCESS

**1. Findings for October-December 2004
(for patients < 18 years)**

31% of patients were dialyzed with an AV fistula (AVF), 11% with an AV graft, and 58% with a catheter during October-December 2004 (TABLE 25). The percent of patients with an AVF, AV graft and catheter by selected patient characteristics is shown in Table 25. Opportunities for improvement in the use of AVF exist for all groups.

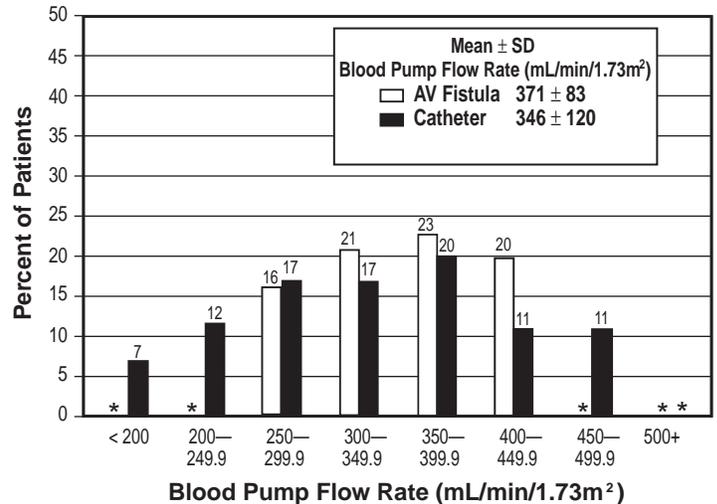
TABLE 25: Vascular access type for all pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2004, by selected patient characteristics. 2005 ESRD CPM Project.

| Patient Characteristics | Percent of Patients with | | |
|-------------------------------------|--------------------------|-----------|-----------|
| | AV Fistula | AV Graft | Catheter |
| TOTAL | 31 | 11 | 58 |
| GENDER | | | |
| Males | 36 | 10 | 53 |
| Females | 24 | 12 | 64 |
| RACE | | | |
| American Indian/ Alaska Native | * | * | * |
| Asian/Pacific Islander | * | * | 71 |
| Black | 28 | 16 | 56 |
| White | 33 | 9 | 58 |
| Other/Unknown | 25 | * | 61 |
| ETHNICITY | | | |
| Hispanic | 35 | 9 | 56 |
| Non-Hispanic | 29 | 12 | 59 |
| AGE GROUP (years) | | | |
| < 12 | 16 | 8 | 76 |
| 12 to <18 | 35 | 12 | 52 |
| DURATION of DIALYSIS (years) | | | |
| < 0.5 | 13 | * | 85 |
| 0.5-0.9 | 36 | * | 57 |
| 1.0-1.9 | 38 | 10 | 52 |
| 2.0-2.9 | 35 | * | 53 |
| 3.0-3.9 | 35 | * | 46 |
| 4.0+ | 33 | 22 | 45 |

NOTE: Percentages may not add up to 100% due to rounding.
*Value suppressed because n < 11.

Facility staff reported either the delivered blood pump flow rate (BFR) 60 minutes after the start of the dialysis session or the average delivered BFR. The mean ± SD delivered BFR 60 minutes after the start of the dialysis session (n=314) was 356 ± 109 mL/min/1.73 m². The delivered BFR averaged over the entire dialysis session (n=340) was 360 ± 112 mL/min/1.73m². The mean ± SD delivered BFR 60 minutes after the start of the dialysis session was lower for patients dialyzed with a catheter compared to patients dialyzed with an AV fistula (FIGURE 57).

Figure 57: 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 2004. 2005 ESRD CPM Project.



* Values suppressed because n < 11.

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).

396 (58%) patients had a catheter as their current access in late 2004. In patients who had catheters for hemodialysis access, no AVF or AV graft was planned for 43% of the patients, another 33% had no AVF or AV graft created at the end of 2004, and an AVF had been created but was not ready to cannulate for 10% (TABLE 26). 4% of patients were not candidates for AVF or AV graft placement as all sites had been exhausted.

Table 26: Reasons for catheter placement in all pediatric (aged < 18 years) in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2004. 2005 ESRD CPM Project.

| Reason | n | (%) |
|---|------------|--------------|
| TOTAL | 396 | (100) |
| No fistula or graft surgically planned | 171 | (43) |
| Patient size too small for AV fistula/graft | 71 | |
| Physician preference | 39 | |
| Patient preference | 38 | |
| Renal transplantation scheduled | 28 | |
| Peripheral vascular disease | * | |
| Fistula maturing, not ready to cannulate | 41 | (10) |
| Graft maturing, not ready to cannulate | * | |
| No fistula or graft surgically created at this time | 132 | (33) |
| All fistula or graft sites in this patient's body have been exhausted | 14 | (4) |
| Temporary interruption of fistula due to clotting or revisions | 11 | (3) |
| Temporary interruption of graft due to clotting or revisions | * | |
| Other | 14 | (4) |

NOTE: Percentages may not add up to 100% due to rounding.
*Value suppressed because n < 11.

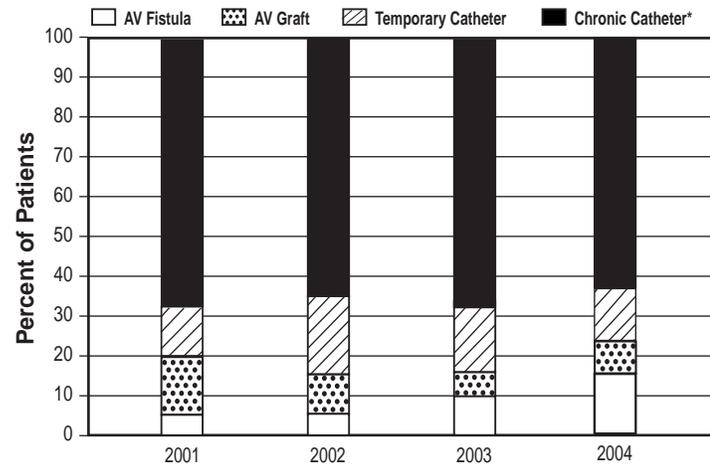
47% of patients (n=325) were dialyzed with a chronic catheter, defined as the continuous use of a catheter 90 days or longer, during October-December 2004.

48% of patients (138/286) 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, 36% were monitored with dynamic venous pressure, 26% with static venous pressure, 23% with the dilution technique, and 20% had other types of monitoring (groups not mutually exclusive).

2. Findings for October-December 2004 compared to previous study periods (for patients < 18 years)

A higher percent of patients aged 11 years or younger was dialyzed with an AVF in late 2004 compared to late 2001 (16% vs. 6%) (FIGURE 58). A lower percent of patients was dialyzed with a catheter in late 2004 compared to late 2001 (76% vs. 80%) (FIGURE 58). Fewer patients were dialyzed with a chronic catheter for 90 days or longer in late 2004 compared to late 2001 (68% in 2001 and 63% in 2004).

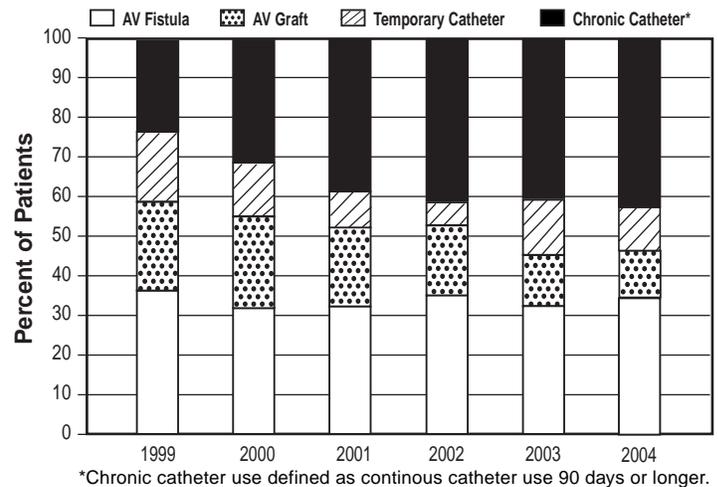
Figure 58: Vascular access type for pediatric (< 12 years) in-center hemodialysis patients on their last hemodialysis session during the study period, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.



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

The trend for vascular access use among patients 12 to < 18 years old is shown in Figure 59. In late 2004, a higher percent of patients in this age group had an AV fistula as their vascular access in late 2004 compared to patients 0-11 years old (35% vs. 16%, respectively). Chronic catheter use was lower among patients 12 to < 18 years old compared to patients 0 to 11 years old in late 2004 (42% vs. 63%, respectively) (FIGURES 58, 59).

Figure 59: 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 2004 compared to previous study periods. 2005 ESRD CPM Project.



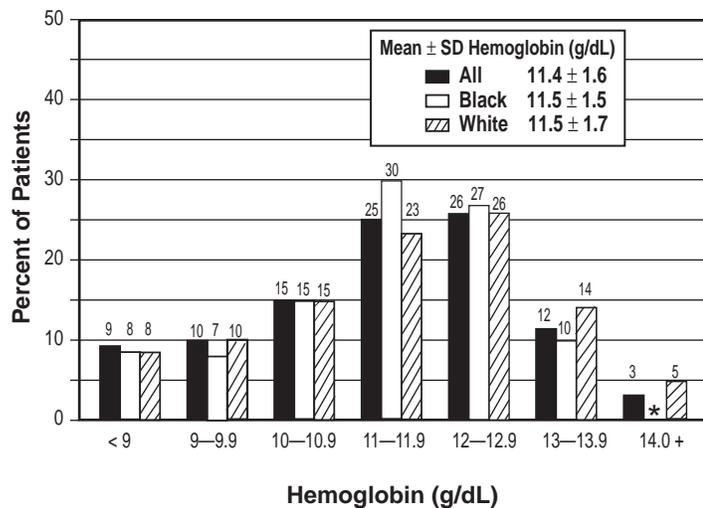
*Chronic catheter use defined as continuous catheter use 90 days or longer.

C. ANEMIA MANAGEMENT

**1. Findings for October-December 2004
(for patients < 18 years)**

The mean ± SD hemoglobin for all patients in the sample was 11.4 ± 1.6 g/dL (114 ± 16 g/L) (FIGURES 12, 60, TABLE 27). The distributions of mean hemoglobin values for all patients, and by race, are shown in Figure 60. The mean hemoglobin values and distribution of hemoglobin values by gender, race, ethnicity, age, duration of dialysis, access type, and mean spKt/V and serum albumin concentrations are shown in Table 27.

Figure 60: Distribution of mean hemoglobin values (g/dL) for all pediatric (aged < 18 years) in-center hemodialysis patients, by race, October-December 2004. 2005 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.
* Values suppressed because n < 11.

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 19%. 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 and higher in patients with a catheter or an AV graft access compared to patients dialyzed with an AVF. 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).

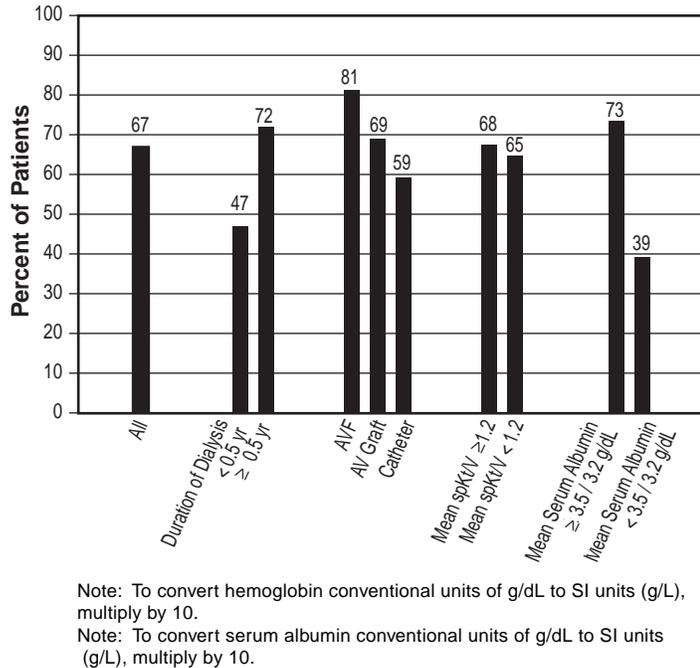
TABLE 27: Mean hemoglobin values (g/dL) and distribution of hemoglobin values for all pediatric (aged < 18 years) in-center hemodialysis patients, by patient characteristics, October-December 2004. 2005 ESRD CPM Project.

| Patient Characteristic | Mean hemoglobin (g/dL) | Percent of patients with hemoglobin values | | | | | | |
|-------------------------------------|------------------------|--|-----------|-----------|-----------|-----------|-----------|----------|
| | | < 9 | 9-9.9 | 10-10.9 | 11-11.9 | 12-12.9 | 13-13.9 | 14+ |
| TOTAL | 11.4 | 9 | 10 | 15 | 25 | 26 | 12 | 3 |
| GENDER | | | | | | | | |
| Males | 11.6 | 7 | 9 | 14 | 24 | 30 | 12 | 4 |
| Females | 11.2 | 12 | 10 | 15 | 26 | 22 | 12 | * |
| RACE | | | | | | | | |
| American Indian/ Alaska Native | * | * | * | * | * | * | * | * |
| Asian/Pacific Islander | 11.1 | * | * | * | * | * | * | * |
| Black | 11.5 | 8 | 7 | 15 | 30 | 27 | 10 | * |
| White | 11.5 | 8 | 10 | 15 | 23 | 26 | 14 | 5 |
| Other/Unknown | 10.6 | 21 | * | * | * | 21 | * | * |
| ETHNICITY | | | | | | | | |
| Hispanic | 11.4 | 8 | 12 | 16 | 25 | 24 | 13 | * |
| Non-Hispanic | 11.5 | 10 | 8 | 15 | 25 | 27 | 11 | 4 |
| AGE GROUP (years) | | | | | | | | |
| 0-4 | 10.8 | * | * | * | * | * | * | * |
| 5-9 | 11.0 | * | 15 | 22 | 28 | 19 | * | * |
| 10-14 | 11.4 | 9 | 10 | 17 | 26 | 24 | 9 | * |
| 15 to < 18 | 11.6 | 8 | 7 | 11 | 25 | 30 | 16 | * |
| DURATION OF DIALYSIS (years) | | | | | | | | |
| < 0.5 | 10.7 | 21 | 16 | 16 | 17 | 18 | * | * |
| 0.5-0.9 | 11.9 | * | * | 11 | 28 | 29 | 15 | * |
| 1.0-1.9 | 11.8 | * | * | 11 | 29 | 34 | 14 | * |
| 2.0-2.9 | 11.7 | * | * | * | 27 | 31 | * | * |
| 3.0-3.9 | 11.4 | * | * | * | 37 | * | * | * |
| 4.0+ | 11.2 | 8 | 12 | 21 | 22 | 24 | 12 | * |
| ACCESS TYPE | | | | | | | | |
| AV Fistula | 12.0 | * | 6 | 11 | 25 | 35 | 17 | * |
| AV Graft | 11.3 | * | * | * | 27 | 31 | * | * |
| Catheter | 11.2 | 13 | 11 | 18 | 25 | 20 | 10 | 3 |
| MEAN spKt/V | | | | | | | | |
| ≥ 1.2 | 11.5 | 7 | 10 | 15 | 24 | 27 | 13 | 3 |
| < 1.2 | 11.3 | * | * | 15 | 29 | 22 | * | * |
| MEAN SERUM ALBUMIN (g/dL) | | | | | | | | |
| ≥ 3.5/3.2 (BCG/BCP)^ | 11.6 | 6 | 8 | 14 | 26 | 30 | 13 | 4 |
| < 3.5/3.2 (BCG/BCP) | 10.4 | 22 | 18 | 20 | 19 | 12 | * | * |

* Values suppressed because n < 11.
^ BCG/BCP = bromcresol green/bromcresol 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 61.

Figure 61: 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 2004. 2005 ESRD CPM Project.



95% of patients were prescribed ESAs during the study period. Of the patients prescribed epoetin, 91% were prescribed epoetin by the IV route; and 10% by the SC route (groups not mutually exclusive). The mean \pm SD weekly epoetin dose for patients prescribed epoetin by the IV route was 364 ± 358 units/kg/week; by the SC route, 275 ± 241 units/kg/week.

The mean \pm SD transferrin saturation for these patients was $29 \pm 15\%$. 71% of patients had a mean transferrin saturation $\geq 20\%$. The mean \pm SD serum ferritin concentration was 476 ± 500 ng/mL. 81% of patients had a mean serum ferritin concentration ≥ 100 ng/mL; 19% of patients had a mean serum ferritin concentration > 800 ng/mL during the study period. 9% (n=63) of patients had a mean transferrin saturation $< 20\%$ and a mean serum ferritin < 100 ng/mL.

77% 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 \pm SD administered IV iron dose was 244 ± 192 mg/month. The mean \pm SD administered IV iron dose was 6 ± 6 mg/kg/month. For the subset of patients with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL (n=63 or 9% of patients), only 63% were prescribed IV iron at least once during the three-month study period.

2. Findings for October-December 2004 compared to previous study periods (for patients < 18 years)

The mean \pm SD hemoglobin for patients aged 0 to < 18 increased from 11.2 ± 1.6 g/dL (112 ± 16 g/L) to 11.4 ± 1.6 (114 ± 16 g/L) from late 2001 to late 2004. 62% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) in late 2001 and 67% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) in late 2004 (FIGURES 62, 63). 19% of patients aged 18 years or younger had a mean hemoglobin < 10 g/dL (100 g/L) in late 2004 compared to 22% in late 2001. Trends in iron management indicators for pediatric patients < 18 years are shown in Figure 64.

Figure 62: Percent of pediatric (aged < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by gender, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.

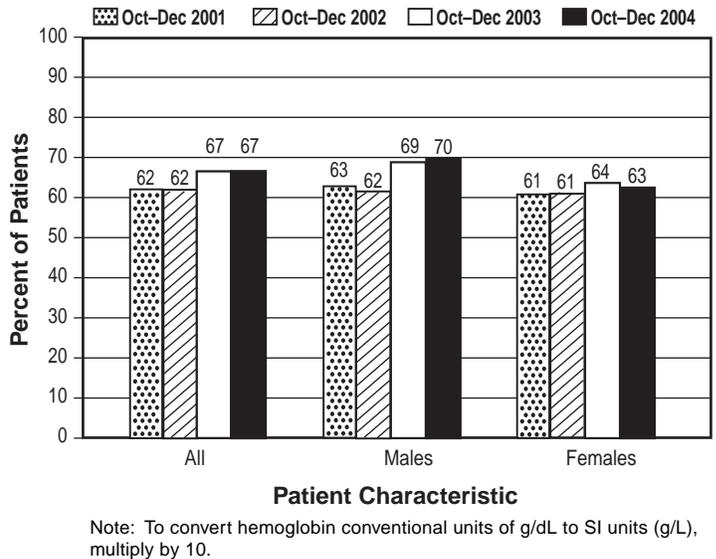


Figure 63: Percent of pediatric (aged < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by race, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.

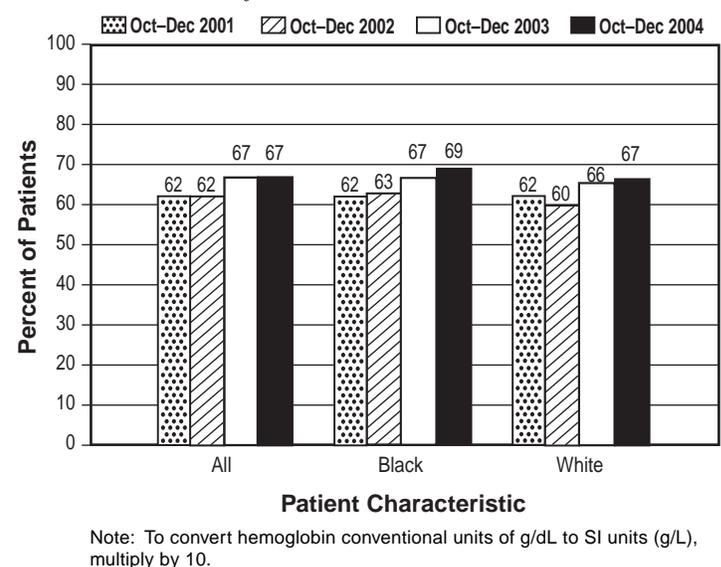


Figure 64: Percent of pediatric (aged < 18 years) in-center hemodialysis patients with specific anemia management indicators, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.

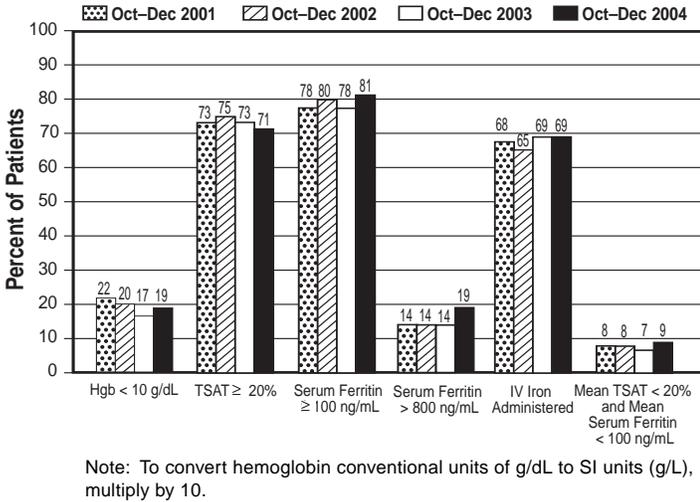
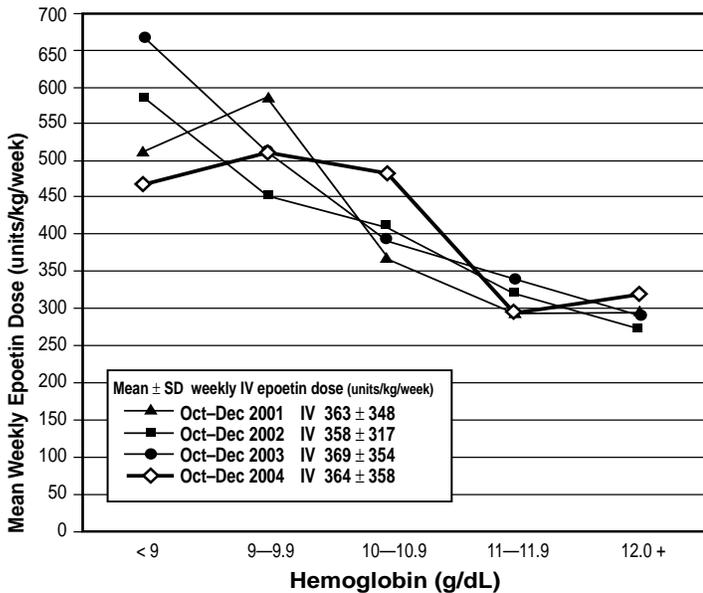


Figure 65 depicts prescribed weekly epoetin dosing (units/kg/week) from late 2001 to late 2004. Prescribed weekly SC epoetin doses were lower than the prescribed weekly IV epoetin doses at most hemoglobin categories examined.

Figure 65: Mean prescribed weekly IV epoetin dose (units/kg/week) for pediatric (aged < 18 years) in-center hemodialysis patients, by hemoglobin category, October-December 2004 compared to previous study periods. 2005 ESRD CPM Project.



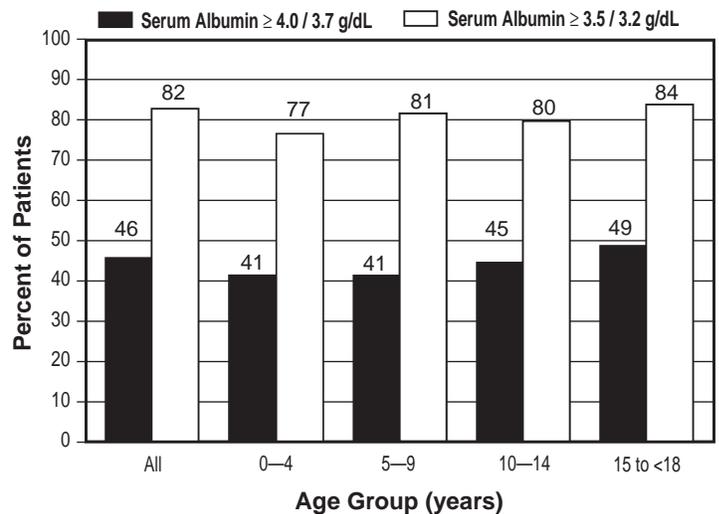
D. SERUM ALBUMIN

1. Findings for October-December 2004 (for patients < 18 years)

The mean ± SD serum albumin value for pediatric patients whose value was determined by the BCG method (n=534) was 3.9 ± 0.5 g/dL (39 ± 5 g/L), and by the BCP method (n=158) was 3.5 ± 0.6 g/dL (35 ± 6 g/L). Nationally, 46% of patients had a mean serum albumin ≥ 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP). 82% of patients had a mean serum albumin ≥ 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP). The percent of patients with mean serum albumin ≥ 4.0/3.7 g/dL (40/37 g/L) and ≥ 3.5/3.2 g/dL (35/32 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 28. The percent of patients with mean serum albumin ≥ 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 ≥ 11 g/dL (110 g/L) compared to patients with lower mean hemoglobin values.

Figure 66 shows the percent of pediatric patients with mean serum albumin ≥ 4.0/3.7 g/dL (40/37 g/L) and ≥ 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) by age group.

Figure 66: Percent of pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin ≥ 4.0/3.7 g/dL (BCG/BCP) and ≥ 3.5/3.2 g/dL (BCG/BCP), by age, October-December 2004. 2005 ESRD CPM Project.



^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 28: 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)[^], and $\geq 3.5/3.2$ g/dL (BCG/BCP), by patient characteristics, October-December 2004. 2005 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 |
| TOTAL | 46 | 82 |
| GENDER | | |
| Males | 54 | 87 |
| Females | 36 | 76 |
| RACE | | |
| American Indian/ Alaska Native | * | * |
| Asian/Pacific Islander | * | 95 |
| Black | 39 | 78 |
| White | 50 | 84 |
| Other/Unknown | 50 | 83 |
| ETHNICITY | | |
| Hispanic | 59 | 87 |
| Non-Hispanic | 40 | 80 |
| AGE GROUP (years) | | |
| 0-4 | 41 | 77 |
| 5-9 | 41 | 81 |
| 10-14 | 45 | 80 |
| 15 to < 18 | 49 | 84 |
| DURATION of DIALYSIS (years) | | |
| < 0.5 | 33 | 71 |
| 0.5-0.9 | 50 | 81 |
| 1.0-1.9 | 56 | 87 |
| 2.0-2.9 | 52 | 88 |
| 3.0-3.9 | 39 | 84 |
| 4.0+ | 44 | 85 |
| ACCESS TYPE | | |
| AV Fistula | 60 | 88 |
| AV Graft | 45 | 91 |
| Catheter | 39 | 78 |
| Catheter ≥ 90 days | 38 | 80 |
| MEAN spKt/V | | |
| ≥ 1.2 | 47 | 83 |
| < 1.2 | 47 | 76 |
| MEAN Hgb (g/dL) | | |
| ≥ 11 | 56 | 89 |
| < 11 | 26 | 67 |

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

* Values suppressed because $n < 11$.

[^]BCG/BCP = bromcresol green/bromcresol purple laboratory methods.

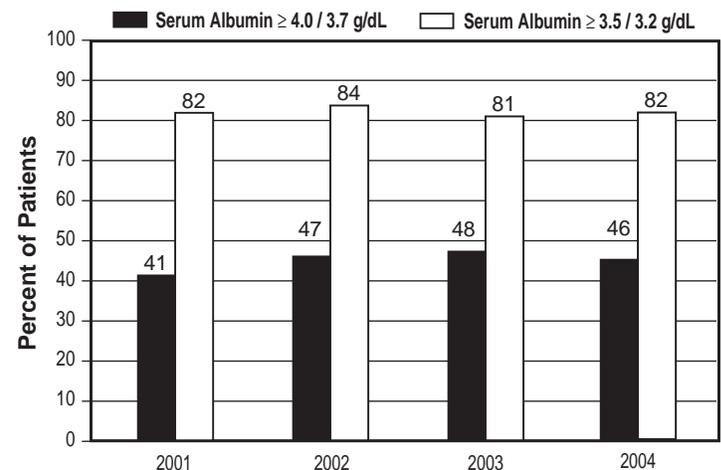
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

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

2. Findings for October-December 2004 compared to previous study periods (for patients < 18 years)

There has been little change in the percent of pediatric patients aged < 18 years achieving mean serum albumin targets from late 2001 to late 2004 (FIGURE 67).

Figure 67: Percent of pediatric (aged < 18 years) 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 2004 compared to previous study periods. 2005 ESRD CPM Project.



[^]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.

VIII. PEDIATRIC PERITONEAL DIALYSIS PATIENTS

This is the first year data were collected for pediatric (aged < 18 years) peritoneal dialysis patients. All patients aged < 18 years identified as receiving peritoneal dialysis on December 31, 2004 were included in this study ($n = 817$). 761 patients (93%) of this group met the case definition and were included in the sample for analysis. (See footnote to Table 6 on pg 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 national findings for pediatric (aged < 18 years) peritoneal dialysis patients for core indicators related to peritoneal dialysis clearance, anemia management and serum albumin.

A. CLEARANCE

**1. Findings for October 2004 – March 2005
(for patients < 18 years)**

There were 20 patients categorized as CAPD patients and 488 patients categorized as cycler patients during the study period. Tidal peritoneal dialysis patients (n = 54) were excluded from the peritoneal dialysis clearance 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 clearance measures (weekly Kt/V_{urea} or weekly creatinine clearance) for 466 (66%) of the 707 patients included for these analyses during the 2005 study period. For calculated clearance measures, total body water was calculated using a formula validated in pediatric peritoneal dialysis patients (32).

Table 29 depicts the percent of CAPD and cycler patients with a mean calculated weekly Kt/V_{urea} and a mean calculated weekly creatinine clearance meeting certain targets. 72% of cycler patients with a daytime dwell had a mean calculated weekly Kt/V_{urea} and 24% had a mean calculated weekly creatinine clearance that met certain targets during the 2005 study period (TABLE 29). 63% of cycler patients without a daytime dwell had a mean calculated weekly Kt/V_{urea} ≥ 2.2 during the 2005 study period (TABLE 29).

TABLE 29: Description of peritoneal dialysis clearance for pediatric (aged < 18 years) peritoneal dialysis patients, by modality, October 2004 – March 2005. 2005 ESRD CPM Project.

| Weekly Kt/V _{urea} | CAPD Patients ≥ 2.0 | Cycler Patients with daytime dwell ≥ 2.1 | Cycler Patients no daytime dwell ≥ 2.2 |
|-----------------------------|---------------------|--|--|
| % meeting target | 65% | 72% | 63% |
| Mean ± SD | 2.46 ± 0.75 | 2.54 ± 0.75 | 2.36 ± 0.93 |
| Median | 2.49 | 2.43 | 2.45 |

| Weekly creatinine clearance (L/week/1.73m ²) | CAPD Patients ≥ 60 | Cycler Patients with daytime dwell ≥ 63 | Cycler Patients no daytime dwell ≥ 66 |
|--|--------------------|---|---------------------------------------|
| % meeting target | * | 24% | * |
| Mean ± SD | 62.1 ± 34.3 | 53.8 ± 21.9 | 53.2 ± 30.6 |
| Median | 49.1 | 47.8 | 50.1 |

* Value suppressed because n < 11.

^ For CAPD patients, the delivered PD dose target was a weekly Kt/V_{urea} ≥ 2.0 and a weekly creatinine clearance ≥ 60 L/week/1.73m². For cycler patients with a daytime dwell (CCPD patients), the target was a weekly Kt/V_{urea} ≥ 2.1 and a weekly creatinine clearance ≥ 63 L/week/1.73m². For cycler patients with no daytime dwell (NIPD patients), the target was a weekly Kt/V_{urea} ≥ 2.2 and a weekly creatinine clearance ≥ 66 L/week/1.73m².

The mean single fill volume for CAPD patients was 1124 ± 191 mL/m², and for cycler patients, the mean nighttime single fill volume was 1074 ± 329 mL/m². 57% of cycler patients had a mean nighttime single fill volume between 900 – 1299 mL/m², while 26% had a mean single nighttime fill volume of less than 900 mL/m² and 17% had a mean single nighttime fill volume of more than 1300 mL/m². Mean weekly Kt/V_{urea} and weekly creatinine clearance by mean single nighttime fill volumes are depicted in Table 30.

TABLE 30: Mean ± SD weekly clearance values by mean nighttime single fill volumes (mL/m²) for pediatric (aged < 18 years) cycler patients, October 2004-March 2005. 2005 ESRD CPM Project.

| Mean nighttime single fill volume | mean ± SD weekly Kt/V _{urea} | mean ± SD weekly creatinine clearance L/week/1.73m ² |
|-----------------------------------|---------------------------------------|---|
| < 900 | 2.44 ± 0.83 | 54.3 ± 25.2 |
| 900-1099 | 2.64 ± 0.79 | 54.0 ± 22.1 |
| 1100-1299 | 2.49 ± 0.65 | 52.4 ± 19.9 |
| 1300+ | 2.49 ± 0.80 | 54.7 ± 25.6 |

18% of patients (n= 124) had one or more PET results within 12 months of or during the study period. The distribution of PET results is depicted in Table 31.

TABLE 31: Distribution of Peritoneal Equilibration Test (PET) results for pediatric (aged < 18 years) peritoneal dialysis patients, October 2004-March 2005. 2005 ESRD CPM Project.

| | n | (%) |
|----------------------------|----|------|
| Low (0.34 – 0.49) | 16 | (13) |
| Low-Average (0.50 – 0.64) | 54 | (44) |
| High-Average (0.65 – 0.81) | 33 | (27) |
| High (0.82 – 1.03) | 19 | (16) |

B. ANEMIA MANAGEMENT

**1. Findings for October 2004- March 2005
(for patients < 18 years)**

The mean ± SD hemoglobin for pediatric (aged < 18 years) peritoneal dialysis patients was 11.6 ± 1.5 g/dL (116 ± 15 g/L). The distributions of mean hemoglobin values for all patients and by race and ethnicity are depicted in Figures 68 and 69. 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 value and weekly Kt/V_{urea} are shown in Table 32. Nationally, 69% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L). Significantly more Whites and Hispanic patients had a mean hemoglobin ≥ 11 g/dL compared to Blacks and non-Hispanic patients (TABLE 32). A larger percentage of patients with higher mean serum albumin values had a mean hemoglobin ≥ 11 g/dL (g/L) compared to patients with lower mean serum albumin values. Nationally, 51% of patients prescribed ESAs 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 14% (FIGURES 68, 69 , TABLE 32). The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was significantly higher in Blacks compared to Whites, for non-Hispanic patients compared to Hispanic patients, and in patients with lower mean serum albumin values compared to patients with higher mean serum albumin values (TABLE 32).

The mean ± SD transferrin saturation for all patients was 30 ± 14 and 77% of patients had mean transferrin saturation ≥ 20%. The mean ± SD serum ferritin concentration was 332 ± 355 ng/mL, with 75% of patients having a mean serum ferritin concentration ≥ 100 ng/mL and 10% of patients having mean serum ferritin > 800 ng/mL. 52 patients (7% of patients) had both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

Figure 68: Distribution of mean hemoglobin values (g/dL) for all pediatric (aged < 18 years) peritoneal dialysis patients, by race, October 2004 – March 2005. 2005 ESRD CPM Project.

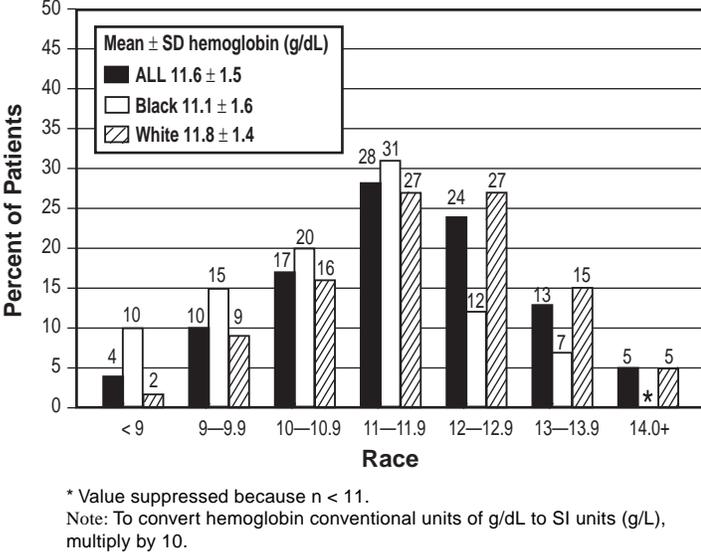


Figure 69: Distribution of mean hemoglobin values (g/dL) for all pediatric (aged < 18 years) peritoneal dialysis patients, by ethnicity, October 2004 – March 2005. 2005 ESRD CPM Project.

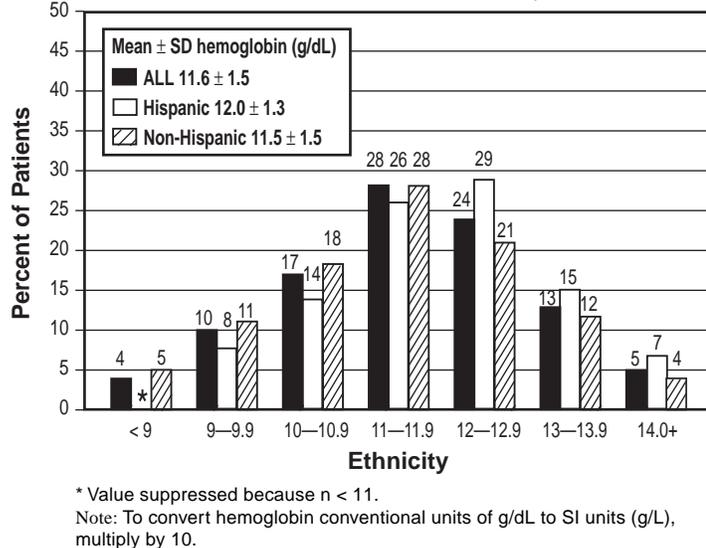


TABLE 32: Mean hemoglobin values (g/dL) and distribution of mean hemoglobin categories for pediatric (aged < 18 years) peritoneal dialysis patients, by patient characteristics, October 2004 – March 2005. 2005 ESRD CPM Project.

| Patient Characteristic | Mean hemoglobin (g/dL) | Percent of patients with hemoglobin values | | | | | | |
|--|------------------------|--|-----------|-----------|-----------|-----------|-----------|----------|
| | | < 9 | 9-9.9 | 10-10.9 | 11-11.9 | 12-12.9 | 13-13.9 | 14+ |
| TOTAL | 11.6 | 4 | 10 | 17 | 28 | 24 | 13 | 5 |
| GENDER | | | | | | | | |
| Males | 11.6 | 3 | 11 | 17 | 28 | 25 | 12 | 5 |
| Females | 11.7 | 5 | 9 | 17 | 28 | 22 | 14 | 5 |
| RACE | | | | | | | | |
| American Indian/Alaska Native | * | * | * | * | * | * | * | * |
| Asian/Pacific Islander | 12.0 | * | * | * | * | * | * | * |
| Black | 11.1 | 10 | 15 | 20 | 31 | 12 | 7 | * |
| White | 11.8 | 2 | 9 | 16 | 27 | 27 | 15 | 5 |
| Other/Unknown | 11.8 | * | * | * | 31 | 31 | * | * |
| ETHNICITY | | | | | | | | |
| Hispanic | 12.0 | * | 8 | 14 | 26 | 29 | 15 | 7 |
| Non-Hispanic | 11.5 | 5 | 11 | 18 | 28 | 21 | 12 | 4 |
| AGE GROUP (years) | | | | | | | | |
| 0-4 | 11.6 | * | 13 | 14 | 32 | 21 | 10 | * |
| 5-9 | 11.5 | * | 12 | 21 | 24 | 20 | 14 | * |
| 10-14 | 11.7 | * | 8 | 16 | 30 | 24 | 14 | 5 |
| 15 to < 18 | 11.7 | * | 9 | 18 | 24 | 26 | 12 | * |
| CAUSE of ESRD | | | | | | | | |
| Congenital/Urologic | 11.7 | * | 11 | 12 | 32 | 24 | 14 | * |
| Other Causes Combined | 11.5 | 4 | 10 | 22 | 28 | 23 | 9 | 4 |
| DURATION of DIALYSIS (years) | | | | | | | | |
| < 0.5 | 11.7 | * | 10 | 20 | 28 | 21 | 13 | * |
| 0.5-0.9 | 11.9 | * | 14 | 9 | 27 | 24 | 16 | 8 |
| 1.0-1.9 | 11.5 | * | 10 | 17 | 32 | 25 | 9 | * |
| 2.0-2.9 | 12.0 | * | * | 14 | 22 | 30 | 18 | * |
| 3.0-3.9 | 11.4 | * | * | * | 32 | * | * | * |
| 4.0+ | 11.4 | * | 11 | 24 | 25 | 20 | 10 | * |
| MEAN WEEKLY Kt/V_{urea} | | | | | | | | |
| ≥ 2.0 | 11.7 | 3 | 8 | 17 | 28 | 26 | 15 | 3 |
| < 2.0 | 11.6 | * | 10 | 15 | 33 | 24 | * | * |
| MEAN SERUM ALBUMIN (g/dL) | | | | | | | | |
| ≥ 3.5/3.2 (BCG/BCP) [^] | 11.8 | 2 | 9 | 16 | 27 | 25 | 15 | 6 |
| < 3.5/3.2 (BCG/BCP) | 11.2 | 7 | 13 | 20 | 29 | 20 | 8 | * |

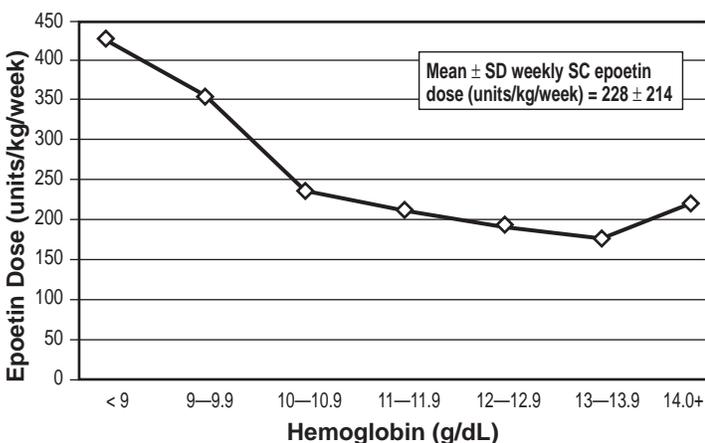
Note: Percentages may not add up to 100% due to rounding
[^] BCG/BCP = bromcresol green/bromcresol purple laboratory methods
 *Value suppressed because n < 11.
 Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

94% of patients were prescribed ESAs during the six-month study period. ESAs were prescribed 92% 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), 96% 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), 96% of the time when mean hemoglobin values were between 13-13.9 g/dL (130-139 g/L), and 89% 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, 97% were prescribed epoetin by the SC route; 6% were prescribed epoetin by the IV route (groups not mutually exclusive). The mean \pm SD weekly epoetin dose for patients prescribed epoetin by the SC route was 228 ± 214 units/kg/week; by the IV route was 317 ± 218 units/kg/week. Weekly prescribed SC epoetin doses tended to decrease as hemoglobin increased (FIGURE 70).

Iron by either the oral or IV route was prescribed at least once during the six months for 84% of the patients in this sample, and three times over the six-month study period for 65% of the patients. Overall, 11% of patients were prescribed IV iron. Of the patients prescribed iron, 95% were prescribed oral iron and 13% were prescribed IV iron (not mutually exclusive categories). Among those patients with mean transferrin saturation < 20% and mean serum ferritin < 100 ng/mL (n=52), 92% were prescribed either oral or IV iron at least once during the six months, and 69% three times over the six-month study period.

Figure 70: Mean prescribed weekly SC epoetin doses (units/kg/week) for pediatric (aged < 18 years) peritoneal dialysis patients, by hemoglobin category, October 2004 – March 2005. 2005 ESRD CPM Project.



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

C. SERUM ALBUMIN

1. Findings for October 2004 - March 2005 (for patients < 18 years)

The mean \pm SD serum albumin value for pediatric (aged < 18 years) peritoneal dialysis patients whose value was determined by the BCG method (n=602) was 3.7 ± 0.6 g/dL (37 ± 6 g/L) and by the BCP method (n=156) was 3.4 ± 0.6 g/dL (34 ± 6 g/L). Nationally, 33% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP). 69% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) by the BCG/BCP method (TABLE 33).

The percent of patients with mean serum albumin values $\geq 4.0/3.7$ g/dL (40/37 g/L) and $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) by gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters is shown in Table 33. The percent of patients with a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) tended to be higher for males compared to females, for White patients compared to Black patients, for Hispanics compared to non-Hispanics, and for patients 15 to < 18 years compared to younger patients (TABLE 33). A higher percent of patients with higher mean hemoglobin values tended to have a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) goal compared to patients with lower mean hemoglobin values.

TABLE 33: Percent of pediatric (aged < 18 years) peritoneal dialysis 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 U.S., by patient characteristics, October 2004 – March 2005. 2005 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 |
| TOTAL | 33 | 69 |
| GENDER | | |
| Males | 34 | 70 |
| Females | 31 | 69 |
| RACE | | |
| American Indian/ Alaska Native | * | * |
| Asian/Pacific Islander | * | 73 |
| Black | 26 | 68 |
| White | 35 | 71 |
| Other/Unknown | 36 | 60 |
| ETHNICITY | | |
| Hispanic | 50 | 83 |
| Non-Hispanic | 27 | 65 |
| AGE GROUP (years) | | |
| 0-4 | 20 | 60 |
| 5-9 | 24 | 60 |
| 10-14 | 33 | 71 |
| 15 to < 18 | 50 | 83 |
| CAUSE of ESRD | | |
| Congenital/Urologic | 30 | 74 |
| Other Causes Combined | 29 | 67 |
| DURATION of DIALYSIS (years) | | |
| < 0.5 | 32 | 64 |
| 0.5-0.9 | 35 | 74 |
| 1.0-1.9 | 40 | 70 |
| 2.0-2.9 | 33 | 79 |
| 3.0-3.9 | * | 66 |
| 4.0+ | 25 | 64 |
| Mean Hgb (g/dL) | | |
| ≥ 11 | 37 | 73 |
| < 11 | 23 | 60 |
| MEAN WEEKLY Kt/V_{urea} | | |
| ≥ 2.0 | 34 | 72 |
| < 2.0 | 36 | 71 |
| MODALITY | | |
| CAPD | * | 60 |
| Cycler with daytime dwell | 36 | 73 |
| Cycler with no daytime dwell | 17 | 65 |

[^] BCG/BCP = bromocresol green/bromocresol purple laboratory methods

* Value suppressed because n < 11.

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.

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XI. Appendices

Appendix 1. ESRD Clinical Performance Measures (CPMs) for 2005 Data Collection Effort

Study period for HD patients is Oct, Nov, Dec 2004; for PD patients is Oct, Nov, Dec 2004 and Jan, Feb, Mar 2005

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 2004).

Denominator:

All adult (≥ 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 (≥ 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 ≥ 1.2 during the study period.

Denominator:

All adult (≥ 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 m² body surface area (BSA) and total weekly Kt/V_{urea} 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 2004 and Jan, Feb, Mar 2005).

Denominator:

All adult (≥ 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 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 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 (≥ 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 m² 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 m² or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.

Denominator:

All adult (≥ 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:

- a. 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 2004).
- b. The number of prevalent patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period.

Denominator:

- a. Incident adult (≥ 18 years old) HD patients (defined as those patients initiating their most recent course of HD on or between Jan 1 and Aug 31, 2004) in the sample for analysis.
- b. Prevalent adult (≥ 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 (≥ 18 years old) patients in the sample for analysis.

9. Vascular Access CPM III: Surveillance of Arterial Venous Grafts for Stenosis.

Vascular Access Guideline 10: Surveillance of 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 surveyed for hemodynamically significant stenosis. The DOQI Work Group recommends an organized surveillance approach with regular assessment of clinical parameters of the arterial venous access and dialysis adequacy. Data from the surveillance 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 surveillance 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 survey for stenosis in arterial venous grafts include:

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

Numerator:

The number of patients in the denominator whose AV graft was routinely surveyed (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 (≥ 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 2004 and Oct, Nov, Dec 2004 and Jan, Feb, Mar 2005 for PD patients).

Denominator:

All adult (≥ 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 (≥ 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 (≥ 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 ≥ 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 ≥ 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 ≥ 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 (≥ 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 (≥ 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 $\geq 50\%$ and/or serum ferritin concentration is ≥ 800 ng/mL, intravenous iron should be withheld for up to three months, at which time the iron parameters should be re-measured before intravenous iron is resumed. When the transferrin saturation and serum ferritin concentration have fallen to $< 50\%$ 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 (≥ 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 ≥ 800 ng/mL and EXCLUDE patients in first three months of dialysis and prescribed oral iron.

b. All adult (≥ 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 ≥ 800 ng/mL and EXCLUDE patients in first three months of dialysis and prescribed oral iron.

Appendix 2

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005

[Before completing please read instructions at the bottom of this page and on pages 4, 5 and 6]

| | |
|--|--|
| PATIENT IDENTIFICATION <div style="background-color: #cccccc; text-align: center; padding: 20px; margin: 10px 0;"> Place Patient Data Label Here </div> | MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW |
| 12. If this patient is unknown or was not dialyzed in the facility at any time during OCT 2004-DEC 2004 return the blank form to the Network. | |
| 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 | |
| 14. Patient's height (MUST COMPLETE): _____ inches OR _____ centimeters (only for patients < 18 years old, provide date when height was measured: ____ / ____ / ____) <div style="text-align: center;">(mm) (dd) (yyyy)</div> | |
| 15. Did patient have limb amputation(s) prior to Dec. 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 | |
| Individual Completing Form (Please print): First name: _____ Last name: _____ Title: _____ Phone number: (_____) _____ - _____ Fax number: (_____) _____ - _____ | |

INSTRUCTIONS FOR COMPLETING THE IN-CENTER HEMODIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005

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.

- | | |
|--|---|
| <ol style="list-style-type: none"> 1. LAST and first name. 3. SOCIAL Security Number (SSN). 5. GENDER (1=Male; 2=Female). 7. PRIMARY cause of renal failure by CMS-2728 code. 9. ESRD Network number. Do not make corrections to this item. | <ol style="list-style-type: none"> 2. DATE of birth (DOB) as MM/DD/YYYY. 4. HEALTH Insurance Claim Number (HIC), (same as Medicare number). 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). 8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis. 10. Facility's Medicare provider number. 11. The most RECENT date this patient returned to hemodialysis 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 2004 through DEC 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, 2004, if known.
 13. Patient's Ethnicity. Please verify the patient's ethnicity with the patient and check appropriate box.
 14. 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.
 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 Dec. 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 2004-DEC 2004.

| IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005 (CONTINUED) | | | |
|--|--|--|--|
| 18. ANEMIA MANAGEMENT: For each lab question below, enter the 1st pre-dialysis lab value obtained for each month: OCT, NOV, DEC 2004. Include the date each lab was drawn. Enter NF/NP if the lab value cannot be located. | | | |
| | OCT 2004 | NOV 2004 | DEC 2004 |
| A. 1st pre-dialysis laboratory hemoglobin (Hgb) of the month: | _____ . _____ g/dL (If NF/NP go to 18C) Date: ____/____/____ | _____ . _____ g/dL (If NF/NP go to 18C) Date: ____/____/____ | _____ . _____ g/dL (If NF/NP go to 18C) Date: ____/____/____ |
| B.1.a. Did the patient have Epoetin prescribed at any time during the 28 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 have Darbepoetin (Aranesp™) prescribed at any time during the 28 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/28 days for the 28 days immediately BEFORE the Hgb in 18A was drawn? | Darbepoetin: _____ mcg/28 days | Darbepoetin: _____ mcg/28 days | Darbepoetin: _____ mcg/28 days |
| 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 (28 days) was Darbepoetin prescribed? | Darbepoetin: _____ per 28 days | Darbepoetin: _____ per 28 days | Darbepoetin: _____ per 28 days |
| 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. 1st pre-dialysis serum ferritin concentration of the month: | _____ ng/mL Date: ____/____/____ | _____ ng/mL Date: ____/____/____ | _____ ng/mL Date: ____/____/____ |
| D. 1st pre-dialysis % transferrin saturation (TSAT) of the month: | _____ % Date: ____/____/____ | _____ % Date: ____/____/____ | _____ % Date: ____/____/____ |
| 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 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 2005 (CONTINUED)

19. SERUM ALBUMIN: Enter the 1st pre-dialysis serum albumin obtained for each month: OCT, NOV and DEC 2004. Include the date the serum albumin was drawn. Enter NF/NP if the lab value cannot be located. Check the method used (BCG brom-cresol green or BCP/bromcresol purple) by the lab to determine serum albumin. If lab method unknown, please call lab to find out.

| | OCT 2004 | NOV 2004 | DEC 2004 |
|---|---|---|---|
| A. 1st pre-dialysis serum albumin of the month: | _____ . _____ g/dL Date: ____/____/____ | _____ . _____ g/dL Date: ____/____/____ | _____ . _____ g/dL Date: ____/____/____ |
| 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 |

20. ADEQUACY: Enter the information requested below for the dialysis session when the 1st labs of the month were drawn and used to measure adequacy for each month: OCT, NOV, DEC 2004. Include the date the labs were drawn. Enter NF/NP if the information cannot be located.

| | OCT 2004 | NOV 2004 | DEC 2004 |
|--|--|--|--|
| A. How many times per week was this patient prescribed to receive dialysis during the week prior to when the pre and post BUNs were drawn? | _____ times per week | _____ times per week | _____ times per week |
| B. 1st recorded URR of the month: | _____ . _____ % Date: ____/____/____ | _____ . _____ % Date: ____/____/____ | _____ . _____ % Date: ____/____/____ |
| C. 1st recorded single-pool Kt/V of the month: | _____ . _____ Date: ____/____/____ | _____ . _____ Date: ____/____/____ | _____ . _____ Date: ____/____/____ |
| D. Method used to calculate the single-pool Kt/V in 20C: (If unknown, please ask Medical Director) | <input type="checkbox"/> Urea Kinetic Modeling <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"/> Urea Kinetic Modeling <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"/> Urea Kinetic Modeling <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. 1st pre-dialysis BUN value of the month: | _____ mg/dL Date: ____/____/____ | _____ mg/dL Date: ____/____/____ | _____ mg/dL Date: ____/____/____ |
| G. 1st post-dialysis BUN value of the month: (both the pre & post dialysis BUN must be drawn on the same day) | _____ mg/dL Date: ____/____/____ | _____ mg/dL Date: ____/____/____ | _____ mg/dL Date: ____/____/____ |
| 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 (BFR) @ 60 minutes after start of dialysis session or average delivered BFR when BUNs above drawn: | _____ mL/min <input type="checkbox"/> 60 min. after start of dialysis <input type="checkbox"/> average delivered BFR | _____ mL/min <input type="checkbox"/> 60 min. after start of dialysis <input type="checkbox"/> average delivered BFR | _____ mL/min <input type="checkbox"/> 60 min. after start of dialysis <input type="checkbox"/> average delivered BFR |
| 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 2005 (CONTINUED)

21. VASCULAR ACCESS: What type of access was used on the last hemodialysis session on or between 10/1/2004 and 12/31/2004 at the patient's primary in-center facility? Check only one of the following access types and follow the corresponding directions.

AV Fistula

Graft

If you checked AV Fistula or Graft, please answer questions 1 and 2 at the right. (See instructions on page 6).

If patient had AV Fistula or Graft:

1. Was routine surveillance for the presence of stenosis performed between 10/1/04 and 12/31/04?
 Yes No Unknown
2. If answer to question 1 is "Yes," please check all methods of surveillance (below) that were utilized.
 - Color-Flow Doppler at least once between 10/1/04 and 12/31/04
 - Static Venous Pressure at least once every 2 weeks between 10/1/04 and 12/31/04
 - Dynamic Venous Pressure every HD session between 10/1/04 and 12/31/04
 - Dilution Technique at least once between 10/1/04 and 12/31/04
 - Other _____

Catheter

Port Access

If you checked Catheter or Port Access, please answer questions 1 and 2 at the right.

If patient had a catheter or port access:

1. Reason for catheter or port access:
 - Fistula maturing, not ready to cannulate (both arterial and venous limb)
 - Graft maturing, not ready to cannulate (both arterial and venous limb)
 - Temporary interruption of fistula due to clotting or revisions
 - Temporary interruption of graft due to clotting or revisions
 - All fistula or graft sites have been exhausted
 - No fistula or graft surgically created at this time
2. Had a catheter or port access been used exclusively for the past 90 days or longer?
 Yes No Unknown

No fistula or graft surgically planned

(check all that apply)

Peripheral vascular disease

Patient size too small for AV fistula or graft

Renal transplantation scheduled

Patient preference

Physician/Surgeon preference

Other _____

Unknown

22. Did the patient FIRST start hemodialysis during January 1, 2004-August 31, 2004 (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). Yes (answer 22A-B) No

A. What type of access was in use at the **Initiation** of a maintenance course of hemodialysis (First hemodialysis was during JAN 1, 2004-AUG 31, 2004.)? AV Fistula Graft Catheter Port Access Unknown

B. What type of access was in use 90 days later? AV Fistula Graft Catheter Port Access Unknown

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, 2004 through DEC 31, 2004. Do not leave any items blank. Enter NF/NP if the information cannot be located.

18A: Enter the patient's 1st pre-dialysis hemoglobin (Hgb) for each month OCT, NOV, DEC 2004. Include the date the lab was drawn. If not found or not performed during the month, enter NF/NP.

18B.1: Check the appropriate box to indicate if the patient had EPOETIN prescribed at anytime during the 28 days BEFORE the date of the hemoglobin in 18A or had DARBEOETIN (Aranesp™) prescribed at anytime during the 28 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to prescriber question 18C.

18B.2: If Epoetin was prescribed, enter the PRESCRIBED Epoetin dose, **not the administered dose**, 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. If the patient dialyzed more than three times per week and Epoetin was prescribed for each treatment, add all of the doses for the week together and divide by 3 to calculate the three requested data fields for units/tx. Example: The patient dialyzed five times per week and Epoetin was prescribed 10,000 units for each treatment. Calculate as follows: 10,000 units/tx X 5 tx/week = 50,000 units/week, 50,000 units/week ÷ 3 = 16,667 units/tx for the three requested data fields for units/tx.

If **Darbepoetin** (Aranesp™) was prescribed, enter the PRESCRIBED Darbepoetin dose, **not the administered dose**, in micrograms per month during the 28 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 the purposes of this collection, a "Hold" order will be considered a 0 mcg/month prescribed dose.)

| IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005 (CONTINUED) |
|--|
| 18.B.3: 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. |
| 18B.4: 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. |
| 18C: Enter the patient's 1st pre-dialysis serum ferritin concentration for each month OCT, NOV, DEC 2004. Include the date the lab was drawn. If a serum ferritin concentration test was not found or not performed during the month, enter NF/NP. |
| 18D: Enter the patient's 1st pre-dialysis % transferrin saturation (TSAT) for each month OCT, NOV, DEC 2004. Include the date the lab was drawn. If a % transferrin saturation (TSAT) test was not found or not performed during the month, enter NF/NP. |
| 18E: Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 2004. If there was no prescription for iron go to question 19. |
| 18F: 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 2004. If the patient received iron by mouth and IV during the month please check both boxes. |
| 18G: 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 2004. |
| 19A: Enter the patient's 1st pre-dialysis serum albumin for each month OCT, NOV, DEC 2004. Include the date the lab was drawn. If a serum albumin was not found or not performed during the month, enter NF/NP. |
| 19B: Check the method used by the laboratory to determine the serum albumin value (bromocresol green or bromocresol purple). If you do not know what method the laboratory used, call the lab to find out this information. |
| 20A: Enter the number of times per week the patient was prescribed to receive dialysis in OCT, NOV, and DEC 2004. If the prescription varied during a month, enter the prescription in effect the week prior to when the pre- and post-BUNs were drawn. Do not leave this question blank. |
| 20B: Enter the patient's 1st URR recorded on the lab sheet for each month OCT, NOV, DEC 2004. Include the date the lab was drawn. If not found or not performed during a month, enter NF/NP. |
| 20C: Enter the patient's 1st single-pool Kt/V recorded on the lab sheet for each month OCT, NOV, DEC 2004. Include the date the lab was drawn. If not found or not performed during a month, enter NF/NP. |
| 20D: 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. |
| 20E: 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. |
| 20F & G: Enter the patient's 1st pre- and post-dialysis BUNs for each month. Include the dates the labs were drawn. Both the pre- and post-dialysis BUN must be drawn on the same day. Enter NF/NP if not found or not performed during the month. |
| 20H: 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. |
| 20I: 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 2004. Do not enter the prescribed time on dialysis. |
| 20J: Enter in mL/minutes the delivered blood pump flow rate (BFR) at 60 minutes after the start of the dialysis session or the average delivered BFR when the BUNs in questions 20F&G were drawn for months OCT, NOV, DEC 2004. Do not enter the prescribed blood pump flow rate or the highest achieved blood pump flow rate. Check the box to indicate which BFR is being provided. |

| IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005 (CONTINUED) |
|--|
| <p>20K: 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&G were drawn for OCT, NOV, DEC 2004. If the dialyzer used is not listed on the chart, enter the code for “other” (9999).</p> |
| <p>21: Check only one type of vascular access used on last hemodialysis session on or between OCT 1, 2004 and DEC 31, 2004 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. If a fistula and catheter are being used simultaneously for vascular access, the patient’s access type should be considered catheter. (“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>AV Fistula or Graft: If the vascular access marked for question 21 was an AV fistula or graft indicate if routine surveillance for the presence of stenosis between Oct 1, 2004 and Dec 31, 2004 was done. Routine surveillance is the sequential measurement of access flow OR of venous pressure.</p> <ul style="list-style-type: none"> • Indicate “YES” for this question if you measure access flow OR venous pressure using any of the following: Techniques and frequencies used to measure access flow include: <ol style="list-style-type: none"> a. one of the dilution methods in which the needles are reversed and recirculation is deliberately induced on a regular basis, OR b. conventional Color-Flow Doppler at a minimum of once every three months. Techniques and frequencies used to measure venous pressure include: <ol style="list-style-type: none"> a. dynamic venous pressure measured at every hemodialysis session; uses low blood pump flow rates usually set at 200 mL/min., OR b. static venous pressure measured at a minimum of once every two weeks; performed at zero blood pump flow. • Indicate “NO” for this question if you only conduct (or note) the following clinical assessments: <ol style="list-style-type: none"> a. Prolonged bleeding after needle withdrawal. b. Altered characteristics of thrill or bruit. c. Adequacy measurements using Kt/V or URR. d. Recirculation methods. |
| <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>Catheter or Port Access: If the vascular access marked for question 21 was a catheter or port access, indicate in the appropriate space the reason for the catheter or port access.</p> |
| <p>Continue with question 2 and indicate in the appropriate space if one or more catheters or port accesses had been used continuously in this patient for the past 90 days or longer between OCT 1, 2004 and DEC 31, 2004.</p> |
| <p>Unknown: If the vascular access in question 21 is unknown indicate by checking the “unknown” box and then continue to question 22.</p> |
| <p>22: Check the appropriate space to indicate if the patient FIRST started hemodialysis during January 1, 2004-August 31, 2004 (see date #8 on page 1). These patients would have begun a regular maintenance course of hemodialysis during January 1, 2004-August 31, 2004. DO NOT include patients who have transferred from peritoneal dialysis, had a newly failed transplant, or returned after an episode of regained kidney function, and were placed on maintenance hemodialysis during the time frame January 1, 2004-August 31, 2004. If “Yes”, answer questions 22A-B. If “No”, questions 22A-B should be left blank and the form has been completed.</p> |
| <p>22A: Check the appropriate space to indicate type of vascular access in use upon Initiation of a maintenance course of hemodialysis. Patient’s FIRST hemodialysis would be during the time frame January 1, 2004-August 31, 2004. 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>22B: Check the appropriate space to indicate type of vascular access, for the patient identified in 22A, in use 90 days after 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> |

| PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005 (CONTINUED) | | | |
|---|--|--|--|
| 18. ANEMIA MANAGEMENT: For each lab question below, enter the first lab value obtained for each two-month time period: OCT-NOV 2004, DEC 2004-JAN 2005, FEB-MAR 2005. Include the date each lab was drawn. Enter NF/NP if the lab value cannot be located. | | | |
| | OCT-NOV 2004 | DEC 2004-JAN 2005 | FEB-MAR 2005 |
| A. First laboratory hemoglobin (Hgb) during the two-month time period (If NF/NP go to 18C) | _____ . _____ g/dL Date: ____/____/____ | _____ . _____ g/dL Date: ____/____/____ | _____ . _____ g/dL Date: ____/____/____ |
| B.1.a. Did the patient have a prescription for Epoetin at anytime during the 28 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 have a prescription for Darbepoetin (Aranesp™) at anytime during the 28 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 TOTAL PRESCRIBED Epoetin dose in effect prior to the 28 days BEFORE the Hgb in 18A was drawn? (Instructions on page 5) | Epoetin: _____ units/28 days | Epoetin: _____ units/28 days | Epoetin: _____ units/28 days |
| B.2.b. What was the TOTAL PRESCRIBED Darbepoetin dose in effect prior to the 28 days BEFORE the Hgb in 18A was drawn? (Instructions on page 5) | Darbepoetin: _____ mcg/28 days | Darbepoetin: _____ mcg/28 days | Darbepoetin: _____ mcg/28 days |
| B.3.a. How many doses per month (28 days) of Epoetin was prescribed? | Epoetin: _____ per 28 days | Epoetin: _____ per 28 days | Epoetin: _____ per 28 days |
| B.3.b. How many doses per month (28 days) of Darbepoetin was prescribed? | Darbepoetin: _____ per 28 days | Darbepoetin: _____ per 28 days | Darbepoetin: _____ per 28 days |
| 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 Date: ____/____/____ | _____ ng/mL Date: ____/____/____ | _____ ng/mL Date: ____/____/____ |
| D. First % transferrin saturation (TSAT) during the two-month time period: | _____ % Date: ____/____/____ | _____ % Date: ____/____/____ | _____ % Date: ____/____/____ |
| 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 |
| 19. SERUM ALBUMIN: Enter the first serum albumin obtained for each two-month time period: OCT-NOV 2004, DEC 2004-JAN 2005, FEB-MAR 2005. Include the date the serum albumin was drawn. 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. | | | |
| | OCT-NOV 2004 | DEC 2004-JAN 2005 | FEB-MAR 2005 |
| A. First serum albumin during the two-month time period: | _____ . _____ g/dL Date: ____/____/____ | _____ . _____ g/dL Date: ____/____/____ | _____ . _____ g/dL Date: ____/____/____ |
| 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 |
| 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. | | | |
| | OCT-NOV 2004 | DEC 2004-JAN 2005 | FEB-MAR 2005 |
| 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 2005 (CONTINUED) | | | |
|--|---|---|--|
| <p>21. PD ADEQUACY: The following data are requested for the FIRST PD ADEQUACY determination during the months OCTOBER 2004 through MARCH 2005. Starting with the first adequacy measurement in these months, enter the adequacy measurements/results listed below that were obtained. (Please DO NOT record more than one adequacy measurement done for any one month.) Please read instructions on Pages 5 and 6 before completing this section. Enter NF/NP if information cannot be located.</p> | | <p>22. PERITONEAL DIALYSIS PRESCRIPTION: 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 NF/NP if information cannot be located.</p> | |
| 21. Was PD adequacy measurement done during OCT 2004-MAR 2005? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | Prescription at the time adequacy was measured in 21A |
| 21A. Date of FIRST PD adequacy measurement between 10-1-2004 to 3-31-2005 | ___ / ___ / ___ (mm) (dd) (yyyy) | <p>22A. CAPD PRESCRIPTION (this includes patients with one overnight exchange using an assist device)</p> 1. Number of dialysis days per week 2. Total dialysate volume infused per 24 hours 3. Total number of exchanges per 24 hours (including overnight exchange) | _____ (# days) |
| 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) | | _____ mL/24 hrs |
| 21C. Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs) | _____ . ___ lbs /kgs | | _____ (# exchanges) |
| 21D. Weekly Kt/V _{urea} (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 _____ | <p>22B. CYCLER PRESCRIPTION</p> 1. Number of dialysis days per week 2. Total dialysate volume infused per 24 hours 3. Total dialysis time a. Total nighttime dialysis time b. Total daytime dialysis time c. Total amount of time the patient is dry during 24 hours (Note: 3a+b+c = 24 hours) 4. Nighttime Prescription (excluding last bag fill) a. Volume of a single nighttime exchange b. Number of dialysis exchanges during the nighttime 5. Daytime Prescription (including last bag fill) a. Volume of a single daytime exchange b. Number of dialysis exchanges during the daytime | _____ (# days) |
| 21F. Weekly Creatinine Clearance (dialysate and urine clearance) | _____ . ___ L/wk | | _____ mL/24 hrs |
| 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 | | _____ hrs _____ min _____ hrs _____ min _____ hrs _____ min |
| 21H. 24 hr DIALYSATE volume (prescribed and ultrafiltration) | _____ mL | | _____ mL/exchange _____ (#/nighttime) |
| 21I. 24 hr DIALYSATE urea nitrogen: | _____ . _____ mg/dL | _____ mL/exchange _____ (#/nighttime) | |
| 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 | _____ mL/exchange _____ (#/daytime) | |
| 21L. 24 hr URINE urea nitrogen: | _____ . _____ mg/dL | | |
| 21M. 24 hr URINE creatinine: | _____ . _____ mg/dL | | |
| 21N. SERUM BUN at the time this PD adequacy assessment was done | _____ mg/dL | 6. Does the cycler prescription described above include TIDAL dialysis? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | |
| 21O. SERUM creatinine at the time this PD 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). 2. Date of most recent D/P Cr | _____ . _____ _____ / _____ / _____ (mm) (dd) (yyyy) | <p>22C. Based on the adequacy result from questions 21A-O,</p> 1. Was the collection repeated? 2. Was the prescription changed? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |

| PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FOR 2005: (CONTINUED) | | | |
|--|---|---|---|
| <p>23. PD ADEQUACY: The following data are requested for the SECOND PD ADEQUACY determination during the months NOVEMBER 2004 through MARCH 2005. Starting with the second adequacy measurement in these months, enter the adequacy measurements/results listed below that were obtained. (Please DO NOT 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>24. PERITONEAL DIALYSIS PRESCRIPTION: 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 PD adequacy measurement done during 11-1-2004 to 3-31-2005? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown | | Prescription at the time adequacy was measured in 23A |
| 23A. Date of SECOND PD adequacy measurement between 11-1-2004 to 3-31-2005 | ___ / ___ / ____ (mm) (dd) (yyyy) | 24A. CAPD PRESCRIPTION (this includes patients with one overnight exchange using an assist device) | |
| 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) | 1. Number of dialysis days per week | _____ (# days) |
| 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 _{urea} (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 _____ | 24B. CYCLER PRESCRIPTION | |
| 23F. Weekly Creatinine Clearance (dialysate and urine clearance) | ____. ____ L/wk | 1. Number of dialysis days per week | _____ (# days) |
| 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 | |
| 23I. 24 hr DIALYSATE urea nitrogen: | ____. ____ mg/dL | a. Total nighttime dialysis time | ____ hrs ____ min |
| 23J. 24 hr DIALYSATE creatinine: | ____. ____ mg/dL | b. Total daytime dialysis time | ____ hrs ____ min |
| 23K. 24 hr URINE volume: (If 24 hr urine was not located check NF/NP.) | ____. ____ mL <input type="checkbox"/> NF/NP | c. Total amount of time the patient is dry during 24 hours | ____ hrs ____ min |
| 23L. 24 hr URINE urea nitrogen: | ____. ____ mg/dL | (Note: 3a+b+c = 24 hours) | |
| 23M. 24 hr URINE creatinine: | ____. ____ mg/dL | 4. Nighttime Prescription (excluding last bag fill) | |
| 23N. SERUM BUN at the time this PD adequacy assessment was done | ____. ____ mg/dL | a. Volume of a single nighttime exchange | _____ mL/exchange |
| 23O. SERUM creatinine at the time this PD adequacy assessment was done | ____. ____ mg/dL | b. Number of dialysis exchanges during the nighttime | _____ (#/nighttime) |
| 23P.1. 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) | 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) |
| | | 6. Does the prescription described above include TIDAL dialysis? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| | | 24C. Based on the adequacy result from questions 23A-O, | |
| | | 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 |

| PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005 (CONTINUED) | |
|--|---|
| 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, 2004 through NOV 30, 2004, DEC 1, 2004 through JAN 31, 2005, and FEB 1, 2005 through MAR 31, 2005. Do not leave any items blank. Enter NF/NP if the following information cannot be located. | |
| 18A: | Enter the patient's FIRST hemoglobin (Hgb) value determined by the laboratory for EACH two-month time period. Include the date the lab was drawn. If not found or not performed during the two-month time period, enter NF/NP. |
| 18B.1: | Check the appropriate box to indicate if the patient had a prescription for EPOETIN or DARBEPOETIN (Aranesp™) at anytime during the 28 days BEFORE the date of the hemoglobin value in 18A. If the answer is NO to both, skip to question 18C. |
| 18B.2: | If Epoetin was prescribed, enter the TOTAL PRESCRIBED 4-WEEK Epoetin dose, not the administered dose , in units/28 days given prior to the 28 days 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 unit prescribed dose.) If Darbepoetin (Aranesp™) was prescribed, enter the TOTAL PRESCRIBED 4-WEEK Darbepoetin dose, not the administered dose , in micrograms/28 days prior to the 28 days 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.) |
| 18B.3: | Enter the number of doses per month (28 days) that Epoetin was prescribed OR the number of doses per month (28 days) Darbepoetin was prescribed. |
| 18B4: | 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. |
| 18C: | Enter the patient's FIRST serum ferritin concentration recorded EACH two-month time period. Include the date the lab was drawn. 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). |
| 18D: | Enter the patient's FIRST % transferrin saturation (TSAT) recorded EACH two-month time period. Include the date the lab was drawn. If a % transferrin saturation (TSAT) 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). |
| 18E: | Check either "Yes", "No", or "Unknown" to indicate if iron was prescribed at any time during the two-month time periods. |
| 18F: | 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. |
| 18G: | If the patient was prescribed IV iron, add together all doses that were given during each two-month time period OCT-NOV 2004, DEC 2004-JAN 2005, FEB-MAR 2005 and enter the TOTAL dose of IV iron (in mg) administered . |
| 19A: | Enter the patient's FIRST serum albumin value recorded EACH two-month time period. Include the date the lab was drawn. |
| 19B: | 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. |
| 20A: | 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. |
| 20B: | 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. |
| 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 2004 through MARCH 2005. DO NOT record more than one adequacy measurement done for any one month. | |
| 21. | Check "yes", "no", or "unknown" to indicate if a PD adequacy measurement was done between OCT 1, 2004 through MAR 31, 2005. |
| 21A: | Enter the first date on which PD adequacy of dialysis was assessed for the first measure obtained between OCT 1, 2004 through MAR 31, 2005. DO NOT record more than one PD adequacy measurement done for any one month. |
| 21B: | 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. |
| 21C: | 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. |
| 21D: | Enter the TOTAL WEEKLY Kt/V _{urea} for the first adequacy measurement indicated on 21A between OCT 1, 2004 through MAR 31, 2005. NOTE: Whether or not you have a value for weekly Kt/V _{urea} 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 _{urea} , multiply this result by 7.0 and enter the result in the appropriate space(s). If this patient did not dialyze each day of the week, then multiply the daily Kt/V _{urea} by the number of days the patient did dialyze. |

| PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2005 (CONTINUED) | |
|--|--|
| 21E: | Check the method used to calculate the V in the Kt/V_{urea} measurement; % BW = percent of body weight; Hume and Watson are two nomograms used to calculate V based on several of these parameters - weight, height, age, gender. If method used to calculate V is not known, please call lab to ascertain method. Please do not leave blank. |
| 21F: | Enter the TOTAL WEEKLY CREATININE CLEARANCE for the first adequacy measurement indicated on 21A between OCT 1, 2004 through MAR 31, 2005. 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. |
| 21G: | Check Yes or No if the weekly creatinine clearance was normalized for body surface area (i.e., the result is multiplied by 1.73m ² 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. |
| 21H, I, and J: | 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, 2004 through MAR 31, 2005. 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. |
| 21K, L, and M: | Enter the 24-hour URINE volume, urea nitrogen and creatinine obtained for the first adequacy assessment obtained between OCT 1, 2004 through MAR 31, 2005. 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. |
| 21N, O: | Enter the SERUM BUN and SERUM CREATININE obtained for the first PD adequacy assessment obtained between OCT 1, 2004 through MAR 31, 2005. Enter NF/NP in the appropriate spaces for all time periods when not found or not performed. |
| 21P: | (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 3/31/05 or prior to the first day of peritoneal dialysis. |
| 22: | 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, 2004 through MAR 31, 2005. Complete all items that are applicable. |
| 22A: | 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. |
| 22B: | 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. |
| 22C: | (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 PD adequacy measurement performed between OCT 1, 2004 through MAR 31, 2005. |
| 23: | Check "yes", "no", or "unknown" to indicate if a PD adequacy measurement was done between NOV 1, 2004 through MAR 31, 2005. |
| 23A-O: | See instructions for 21A-21O and complete for second PD adequacy measurement performed between NOV 1, 2004 through MAR 31, 2005. DO NOT record more than one PD adequacy measurement done for any one month. |
| 23P: | 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. |
| 24A-C: | 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, 2004 through MAR 31, 2005. |

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
JFK Federal Building
Boston, MA 02203-0003
(617) 565-3136

Centers for Medicare & Medicaid Services -
Region VI
Division of Clinical Standards and Quality
Room 714
1301 Young Street
Dallas, TX 75202
(214) 767-4443

Centers for Medicare & Medicaid Services -
Region VII
Division of Clinical Standards and Quality,
Medical Review Branch
Richard Bolling Federal Building
601 East 12th Street, Room 242
Kansas City, MO 64106-2808
(816) 426-5746

Centers for Medicare & Medicaid Services -
Region X
Division of Clinical Standards and Quality
2201 Sixth Avenue, Mail Stop (RX-42)
Seattle, WA 98121-2500
(206) 615-2317

ESRD Networks

ESRD Network Organization No. 1
ESRD Network of New England, 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.
11 Park Place, Suite 1503
New York, NY 10007
Region I: NY
(212) 571-8500

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 24th 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
5201 West Kennedy Boulevard
Tampa, FL 33609
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
(323) 962-2020

Appendix 5. ESRD CPM Quality Improvement Committee Members

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* Vascular Access Subcommittee Member

+ Pediatric Subcommittee Member

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

Publications on Adult Patients

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 Financ Rev* 16:129-140, 1995
2. McClellan WM, Helgerson S, Frederick P, Wish J: Implementing the Health Care Quality Improvement Program in the Medicare End-Stage Renal Disease Program: A new era of quality improvement. *Adv Ren Replace Ther* 2:89-95, 1995
3. McClellan Wm: Quality of patient care in the Medicare End-Stage Renal Disease (ESRD) Program: The basis and implementation of the 1994-1997 ESRD Health Care Quality Improvement Program (HCQRP). *Curr Opin Nephrol and Hypertens* 5:224-229, 1996
4. Helgerson SD, McClellan WM, Frederick PR, Beaver SK, Frankenfield DL, McMullan M: Improvement in adequacy of delivered dialysis for adult in-center hemodialysis patients in the United States, 1993 to 1995. *Am J Kidney Dis* 29:851-861,1997
5. Rocco MV, Flanigan MJ, Beaver S, Frederick P, Gentile DE, McClellan WM, et al: Report from the 1995 Core Indicators for Peritoneal Dialysis Study Group. *Am J Kidney Dis* 30:165-173, 1997
6. Flanigan MJ, Rocco MV, Frankenfield DL, Bailie G, Frederick PR, Prowant BF, et al: 1996 Peritoneal Dialysis Core Indicators Report. *Am J Kidney Dis* 32:1-9, 1998
7. Flanigan MJ, Bailie GR, Frankenfield DL, Frederick PR, Prowant BF, Rocco MV: 1996 Peritoneal Dialysis Core Indicators Study: Report on nutritional indicators. *Perit Dial Int* 18:489-496,1998
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9. Frankenfield DL, McClellan WM, Helgerson SD, Lowrie EG, Rocco MV, Owen WF: Relationship between urea reduction ratio, demographic characteristics, and body weight for patients in the 1996 national ESRD Core Indicators Project. *Am J Kidney Dis* 33:584-591, 1999
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11. Frankenfield DL, Prowant BF, Flanigan MJ, Frederick PR, Bailie GR, Helgerson SD, et al: Trends in clinical indicators of care for adult peritoneal dialysis patients in the U.S., 1995-1997. *Kidney Int* 55:1998-2010, 1999
12. Bailie GR, Frankenfield DL, Prowant BF, McClellan WM, Rocco MV: Erythropoietin and iron use in peritoneal dialysis patients. Report from the 1997 HCFA End-Stage Renal Disease Core Indicators Project. *Am J Kidney Dis* 33:1187-1189, 1999
13. Flanigan MJ, Rocco MV, Frankenfield D, Bailie G, Frederick P, Prowant B, et al: 1997 Peritoneal Dialysis Core Indicators Study: Dialysis adequacy and nutritional indicators report. *Am J Kidney Dis* 33(6):e3, 1999
14. Flanigan MJ, Rocco MV, Frankenfield D: Core Indicators Study – Anemia in peritoneal dialysis; Implications for future monitoring. *Semin Dial* 12:157-161, 1999
15. Owen WF Jr., Szczech L, Johnson C, Frankenfield D: National perspective on iron therapy as a clinical performance measure for maintenance hemodialysis patients. *Am J Kidney Dis* 34 S5-S11, 1999 (Suppl 2)
16. Frankenfield DL, Rocco MV, Frederick PR, Pugh J, McClellan WM, Owen WF Jr: Racial/ethnic analysis of selected intermediate outcomes for hemodialysis patients: Results from the 1997 ESRD Core Indicators Project. *Am J Kidney Dis* 34:721-730, 1999
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Supplemental Reports

1994

Supplemental Report #1

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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 ≥ 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 (≥ 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 (≥ 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)

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)

* 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

**APPENDIX 7 2005 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

| Network | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | US |
|---|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|-------------|
| # in sample | 452 | 474 | 479 | 465 | 470 | 477 | 468 | 476 | 475 | 469 | 463 | 446 | 470 | 486 | 479 | 470 | 476 | 484 | 8479 |
| DIALYSIS ADEQUACY | | | | | | | | | | | | | | | | | | | |
| % Pts with mean spKt/V ≥ 1.2 | 94 | 86 | 91 | 92 | 89 | 91 | 90 | 92 | 94 | 91 | 88 | 93 | 90 | 94 | 91 | 92 | 88 | 88 | 91 |
| Median spKt/V | 1.55 | 1.50 | 1.52 | 1.56 | 1.51 | 1.54 | 1.53 | 1.53 | 1.55 | 1.59 | 1.52 | 1.55 | 1.53 | 1.61 | 1.59 | 1.62 | 1.52 | 1.54 | 1.55 |
| % Pts with mean URR ≥ 65% | 91 | 82 | 88 | 89 | 84 | 88 | 88 | 86 | 92 | 89 | 85 | 91 | 86 | 92 | 87 | 89 | 85 | 86 | 87 |
| Median URR % | 74 | 72 | 72 | 73 | 72 | 73 | 73 | 72 | 73 | 74 | 73 | 73 | 72 | 74 | 74 | 75 | 72 | 73 | 73 |
| Median blood pump flow^ (mL/min) | 400 | 400 | 400 | 400 | 400 | 400 | 400 | 417 | 408 | 400 | 416 | 417 | 400 | 400 | 400 | 400 | 400 | 400 | 400 |
| Median dialysis session length (min) | 210 | 210 | 211 | 227 | 210 | 214 | 210 | 225 | 225 | 220 | 210 | 212 | 220 | 236 | 212 | 233 | 198 | 210 | 213 |
| VASCULAR ACCESS | | | | | | | | | | | | | | | | | | | |
| % Prevalent pts with AVF | 49 | 49 | 34 | 38 | 31 | 37 | 43 | 30 | 36 | 36 | 37 | 36 | 35 | 35 | 46 | 57 | 47 | 38 | 39 |
| % Incident pts with AVF | 43 | 43 | 32 | 31 | 22 | 39 | 39 | 25 | 29 | 30 | 36 | 36 | 45 | 34 | 46 | 53 | 57 | 46 | 37 |
| % Prevalent pts with AVG | 24 | 25 | 32 | 31 | 39 | 41 | 27 | 44 | 31 | 30 | 31 | 35 | 35 | 44 | 29 | 20 | 33 | 39 | 34 |
| % pts with AVG and stenosis monitoring | 50 | 51 | 57 | 66 | 62 | 71 | 63 | 78 | 77 | 65 | 62 | 77 | 55 | 68 | 60 | 77 | 83 | 69 | 67 |
| % Prevalent pts with catheter | 28 | 26 | 33 | 31 | 30 | 22 | 30 | 26 | 33 | 33 | 32 | 29 | 31 | 21 | 26 | 23 | 20 | 23 | 27 |
| % Prevalent pts with catheter ≥ 90 days | 21 | 19 | 31 | 24 | 23 | 17 | 23 | 18 | 25 | 21 | 25 | 21 | 21 | 16 | 24 | 15 | 15 | 17 | 21 |

^60 minutes after the start of the dialysis session

**2005 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES (cont.)
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

| Network | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | US |
|---|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| ANEMIA MANAGEMENT | | | | | | | | | | | | | | | | | | | |
| Median hgb (g/dL) | 11.8 | 12.0 | 12.0 | 11.9 | 12.2 | 12.1 | 12.0 | 12.0 | 12.1 | 12.1 | 12.0 | 12.0 | 12.1 | 12.0 | 12.2 | 11.9 | 12.0 | 12.1 | 12.0 |
| % Pts with mean hgb ≥ 11g/dL | 80 | 79 | 84 | 85 | 84 | 84 | 84 | 85 | 83 | 83 | 83 | 83 | 80 | 84 | 84 | 81 | 82 | 87 | 83 |
| % Pts with mean hgb 11-12.0 g/dL [^] | 38 | 30 | 34 | 41 | 30 | 31 | 36 | 38 | 28 | 32 | 32 | 37 | 30 | 35 | 31 | 38 | 34 | 37 | 34 |
| % Pts with mean hgb < 10 g/dL | 7 | 9 | 6 | 5 | 7 | 4 | 6 | 7 | 4 | 8 | 6 | 4 | 7 | 3 | 6 | 3 | 6 | 4 | 6 |
| Median wkly IV epoetin dose units/kg/wk | 215 | 244 | 231 | 193 | 204 | 203 | 226 | 223 | 187 | 193 | 181 | 195 | 199 | 188 | 164 | 178 | 182 | 187 | 197 |
| Median wkly SC epoetin dose units/kg/wk | 147 | 175 | 159 | * | * | 150 | 338 | * | 184 | 136 | 183 | 113 | 197 | 98 | 102 | 117 | 147 | 234 | 146 |
| % Pts rx'd [^] SC epoetin | 2 | 3 | 12 | * | * | 3 | 3 | * | 3 | 5 | 3 | 5 | 3 | 12 | 6 | 8 | 9 | 11 | 5 |

IRON MANAGEMENT

| | | | | | | | | | | | | | | | | | | | |
|--------------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| % Pts with mean TSAT ≥ 20% | 75 | 77 | 74 | 75 | 83 | 83 | 81 | 77 | 78 | 76 | 79 | 74 | 78 | 84 | 81 | 71 | 73 | 85 | 79 |
| Median TSAT % | 24 | 26 | 25 | 25 | 27 | 27 | 28 | 25 | 26 | 26 | 27 | 25 | 26 | 27 | 27 | 25 | 25 | 29 | 26 |
| % Pts with mean ferritin ≥ 100 ng/mL | 91 | 93 | 95 | 92 | 93 | 95 | 93 | 95 | 97 | 95 | 93 | 95 | 96 | 95 | 93 | 94 | 93 | 93 | 94 |
| Median ferritin ng/mL | 502 | 502 | 547 | 512 | 524 | 521 | 533 | 530 | 552 | 552 | 510 | 474 | 554 | 578 | 464 | 414 | 467 | 562 | 514 |
| % Pts rx'd IV iron | 69 | 65 | 75 | 75 | 67 | 72 | 70 | 71 | 74 | 73 | 69 | 73 | 71 | 69 | 70 | 70 | 71 | 63 | 70 |

[^] Among those patients prescribed epoetin * Value suppressed because n < 11 Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

**2005 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES (cont.)
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

| Network | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | US |
|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| ALBUMIN | | | | | | | | | | | | | | | | | | | |
| % Pts with mean serum albumin ≥ 4.0/3.7g/dL (BCG/BCP) ^{^^} | 30 | 31 | 31 | 31 | 37 | 40 | 33 | 37 | 35 | 36 | 34 | 31 | 38 | 38 | 35 | 34 | 41 | 39 | 36 |
| % Pts with mean serum albumin ≥ 3.5/3.2g/dL (BCG/BCP) | 79 | 77 | 79 | 79 | 83 | 82 | 85 | 81 | 81 | 82 | 81 | 82 | 83 | 83 | 84 | 81 | 82 | 85 | 82 |
| Median serum BCG albumin (g/dL) | 3.8 | 3.8 | 3.8 | 3.8 | 3.9 | 3.9 | 3.8 | 3.9 | 3.8 | 3.9 | 3.8 | 3.8 | 3.8 | 3.8 | 3.9 | 3.8 | 3.9 | 3.9 | 3.8 |
| Median serum BCP albumin (g/dL) | 3.3 | 3.5 | 3.8 | 3.3 | * | 3.5 | 3.6 | * | 3.6 | 3.6 | 3.7 | 3.5 | 3.8 | 3.8 | 3.6 | 3.4 | 3.6 | 3.8 | 3.6 |

^{^^}BCG/BCP-Brom cresol Green/Brom cresol Purple Laboratory Methods

* Value suppressed because n < 11

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

Appendix 8. 2005 ESRD Outcome Comparison Tool – Adult In-Center Hemodialysis Patients – National and Network Data are from October – December 2004.

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.

| | U.S. | Network | Facility |
|---|-----------------|---------|----------|
| ADEQUACY OF DIALYSIS | | | |
| Percent of patients with a mean spKt/V ≥ 1.2 | 91% | | |
| Mean \pm SD spKt/V | 1.55 \pm 0.27 | | |
| Mean \pm SD blood pump flow rate (mL/minute) 60 minutes after start of dialysis session | 401 \pm 68 | | |
| Mean \pm SD blood pump flow rate (mL/minute) over entire dialysis session | 394 \pm 62 | | |
| Mean \pm SD dialysis session length (minutes) | 217 \pm 32 | | |
| VASCULAR ACCESS | | | |
| Percent of prevalent patients dialyzed with an AV fistula | 39% | | |
| Percent of incident patients dialyzed with an AV fistula | 37% | | |
| Percent of prevalent patients dialyzed with an AV graft | 34% | | |
| Percent of prevalent patients dialyzed with a catheter | 27% | | |
| Percent of prevalent patients dialyzed with a catheter ≥ 90 days | 21% | | |
| ANEMIA MANAGEMENT | | | |
| Percent of patients with mean Hgb ≥ 11.0 g/dL | 83% | | |
| Percent of targeted [†] patients with mean Hgb 11.0 – 12.0 g/dL | 34% | | |
| Percent of patients with mean Hgb < 10.0 g/dL | 6% | | |
| Mean \pm SD Hgb (g/dL) | 12.0 \pm 1.2 | | |
| Mean \pm SD weekly epoetin dose (units/kg/week) | | | |
| IV | 281 \pm 281 | | |
| SC | 215 \pm 233 | | |
| Percent of patients* prescribed SC epoetin | 5% | | |
| Percent of patients with mean TSAT $\geq 20\%$ | 79% | | |
| Mean \pm SD TSAT (%) | 28 \pm 12 | | |
| Percent of patients with mean serum ferritin concentration ≥ 100 ng/mL | 94% | | |
| Mean \pm SD serum ferritin concentration (ng/mL) | 576 \pm 392 | | |
| Percent of patients prescribed IV iron | 70% | | |
| SERUM ALBUMIN | | | |
| Percent of patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP) | 36% | | |
| Percent of patients with mean serum albumin $\geq 3.5/3.2$ g/dL (BCG/BCP) | 82% | | |
| Mean \pm SD serum albumin (g/dL) | | | |
| BCG | 3.8 \pm 0.4 | | |
| BCP | 3.6 \pm 0.5 | | |

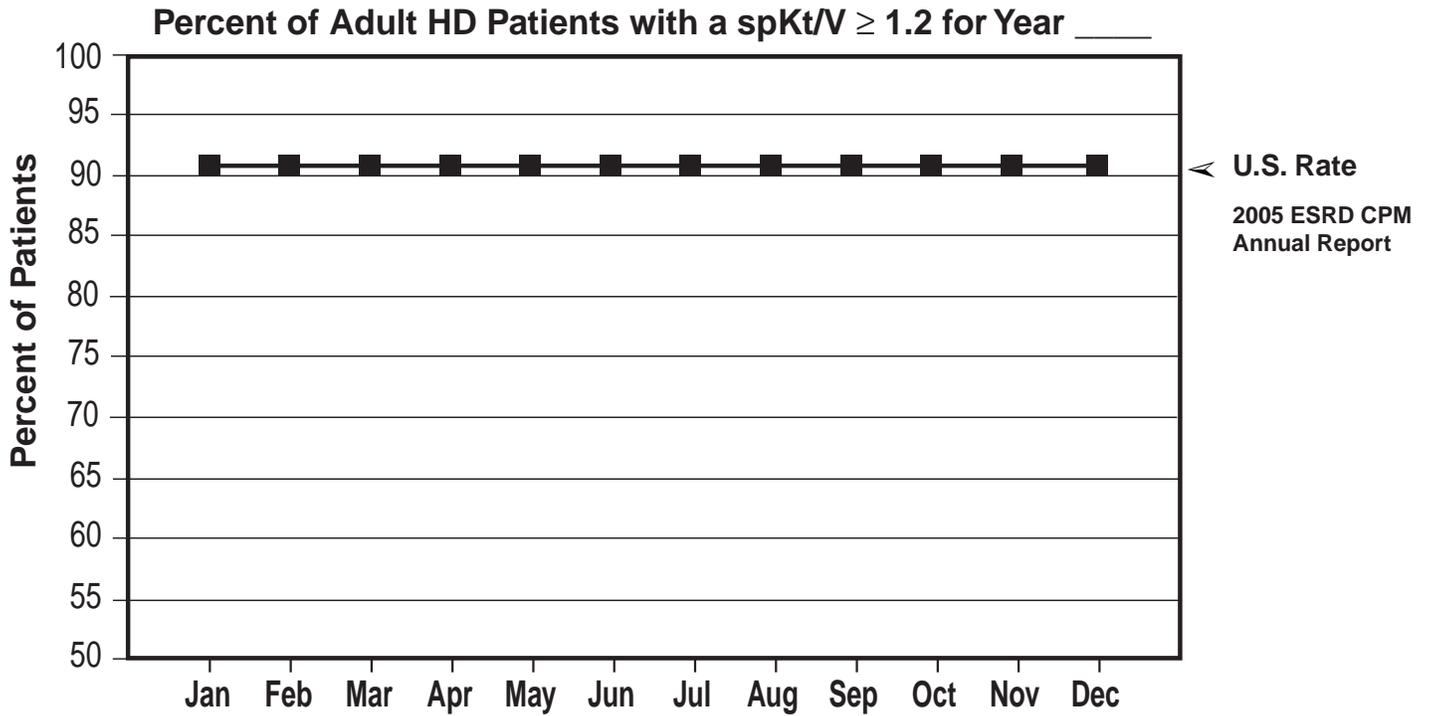
[†] See appendix 1 for complete definition of targeted patients for this CPM.

* Among those patients prescribed epoetin.

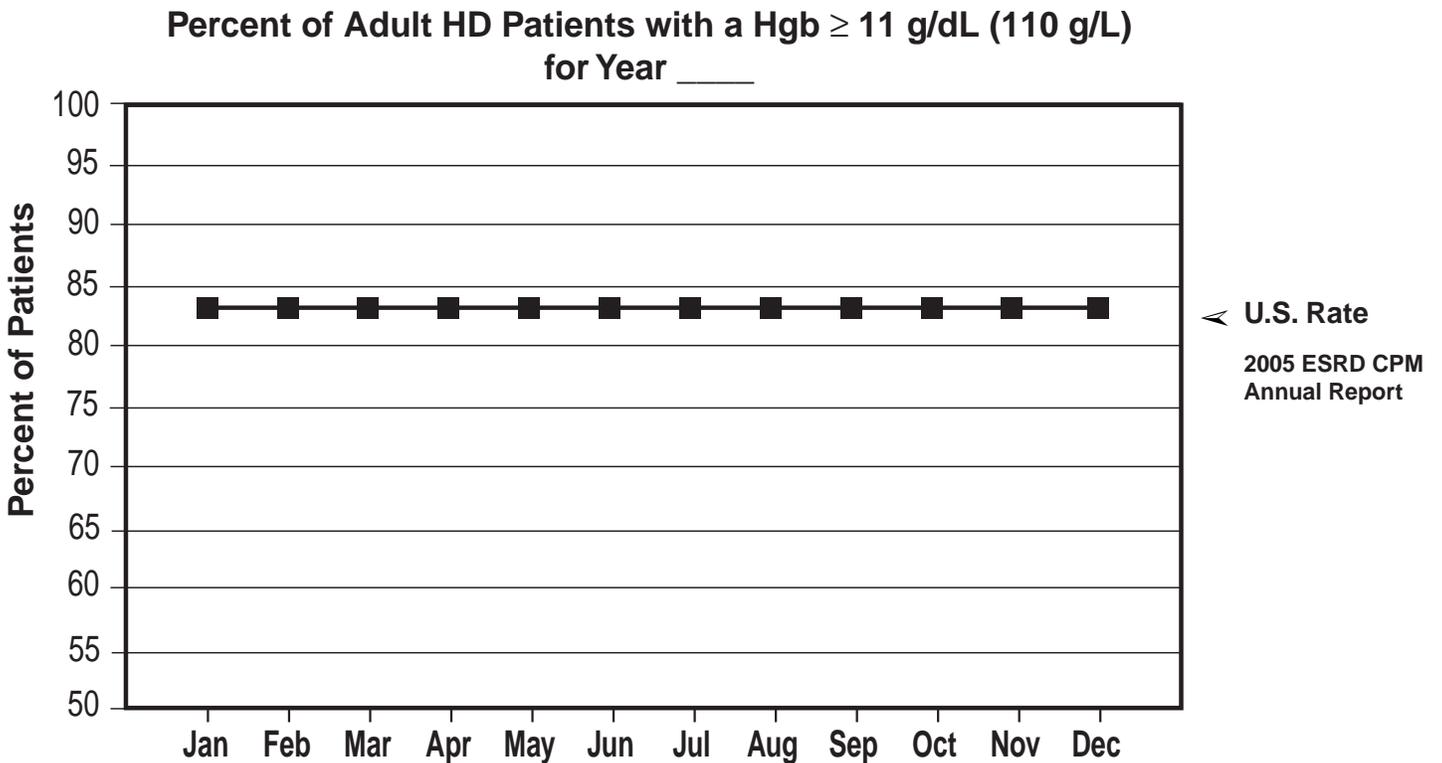
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

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

Use the following chart to plot monthly the percent of adult HD patients in your unit that have a spKt/V ≥ 1.2 (U.S. = 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 ≥ 11 g/dL (110 g/L) (U.S. = 83%). Post the chart in the facility for all to see.



CUT ALONG THIS LINE

Appendix 9. 2005 ESRD Outcome Comparison Tool – Adult Peritoneal Dialysis Patients – National Data are from October 2004 – March 2005.

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

| | U.S. | Facility |
|---|-----------------|----------|
| ADEQUACY OF DIALYSIS | | |
| Percent of patients measured for adequacy at least once during the six month study period (both weekly Kt/V_{urea} and weekly creatinine clearance measured) | 82% | |
| Percent of CAPD patients with mean weekly $Kt/V_{urea} \geq 2.0$ | 66% | |
| Mean \pm SD weekly Kt/V_{urea} for CAPD patients | 2.29 \pm 0.65 | |
| Percent of Cycler patients with a daytime dwell with mean weekly $Kt/V_{urea} \geq 2.1$ | 57% | |
| Mean \pm SD weekly Kt/V_{urea} for Cycler patients with a daytime dwell | 2.23 \pm 0.61 | |
| Percent of Cycler patients without a daytime dwell with mean weekly $Kt/V_{urea} \geq 2.2$ | 60% | |
| Mean \pm SD weekly Kt/V_{urea} for Cycler patients without a daytime dwell | 2.37 \pm 0.77 | |
| ANEMIA MANAGEMENT | | |
| Percent of patients with mean Hgb ≥ 11.0 g/dL | 82% | |
| Percent of targeted [†] patients with mean Hgb 11.0 – 12.0 g/dL | 33% | |
| Percent of patients with mean Hgb < 10.0 g/dL | 5% | |
| Mean \pm SD Hgb (g/dL) | 12.0 \pm 1.3 | |
| Percent of patients* prescribed SC epoetin | 98% | |
| Percent of patients with mean TSAT $\geq 20\%$ | 84% | |
| Mean \pm SD TSAT (%) | 30 \pm 11 | |
| Percent of patients with mean serum ferritin ≥ 100 ng/mL | 87% | |
| Mean \pm SD serum ferritin concentration (ng/mL) | 450 \pm 411 | |
| Percent of patients prescribed IV iron | 25% | |
| SERUM ALBUMIN | | |
| Percent of patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP) | 20% | |
| Percent of patients with mean serum albumin $\geq 3.5/3.2$ g/dL (BCG/BCP) | 62% | |
| Mean \pm SD serum albumin (g/dL) | | |
| BCG | 3.6 \pm 0.5 | |
| BCP | 3.4 \pm 0.6 | |

[†] 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.

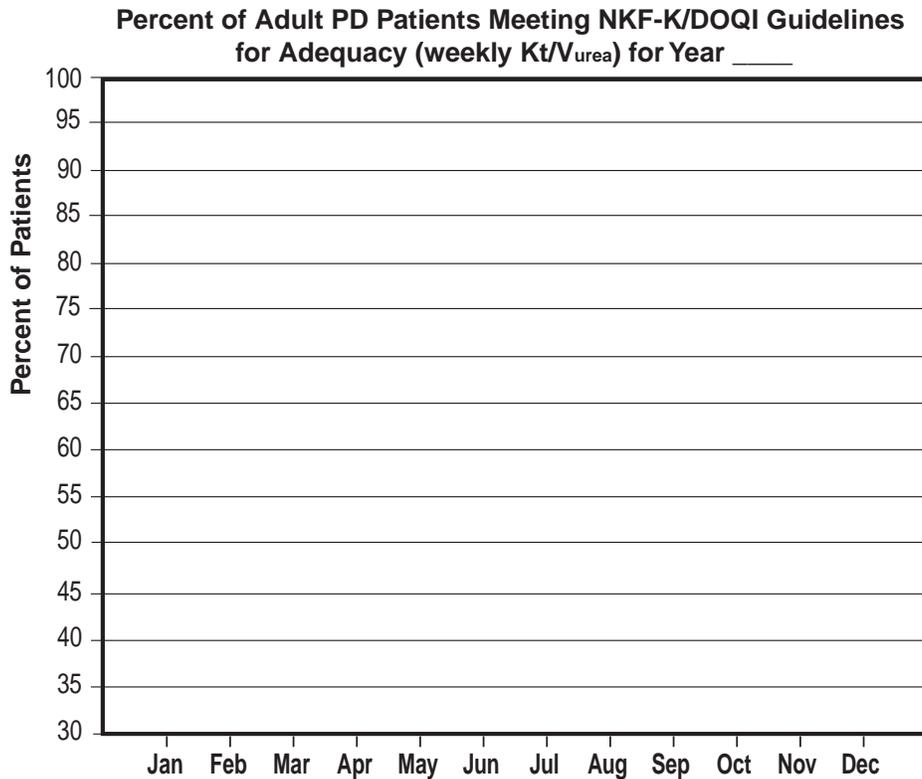
Use the following chart to plot monthly:

The % of adult CAPD patients in your unit that have a $Kt/V_{urea} \geq 2.0$ (U.S. = 66%).

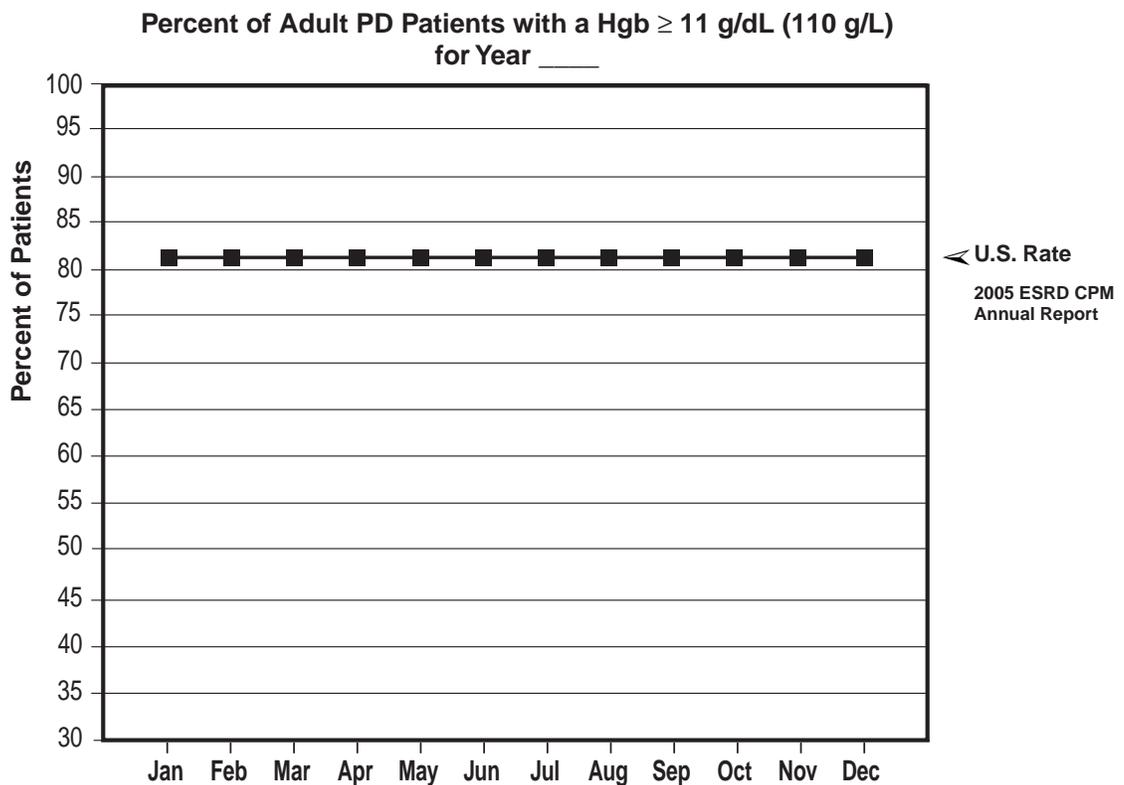
The % of adult Cycler patients with a daytime dwell that have a $Kt/V_{urea} \geq 2.1$ (U.S. = 57%);

The % of adult Cycler patients without a daytime dwell that have a $Kt/V_{urea} \geq 2.2$ (U.S. = 60%).

Post the chart in the facility for all to see.



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



CUT ALONG THIS LINE