

2003 ANNUAL REPORT ESRD CLINICAL PERFORMANCE MEASURES PROJECT

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

DECEMBER 2003



Department of Health and Human Services
Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
Baltimore, Maryland



Data on adult in-center hemodialysis patients are from October–December 2002

Data on adult peritoneal dialysis patients are from October 2002–March 2003

Data on pediatric in-center hemodialysis patients are from October–December 2002

Suggested citation for this report is as follows:

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Note: The clinical data collected for the 2003 ESRD Clinical Performance Measures Project were from the time period of October–December 2002 for the in-center hemodialysis patients and October 2002–March 2003 for the adult peritoneal dialysis patients.

2004 Data Collection Effort

In 2004, we will again collect data for the ESRD Clinical Performance Measures on a national sample of adult in-center hemodialysis, adult peritoneal dialysis, and all pediatric in-center hemodialysis patients.

Any questions about the Project may be addressed to your ESRD Network staff or to members of the ESRD Clinical Performance Measures Quality Improvement Workgroup (APPENDICES 4 & 5).

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

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- The members of the End-Stage Renal Disease (ESRD) Clinical Performance Measures (CPM) Quality Improvement (QI) Committee and the members of the Peritoneal Dialysis, the Vascular Access, and the Pediatric Subcommittees (See Appendix 5).
- The eighteen ESRD Network Organizations throughout the United States (See Appendix 4).
- The following CMS Central Office staff: Diane L. Frankenfield, DrPH, Pamela R. Frederick and Ava Marie Chandler.
- The following staff at The Renal Network, Inc.: Susan A. Stark, Executive Director, Bridget Carson, Assistant Director, Raynel Kinney, RN, CNN, CPHQ, QI Director, Rick Coffin, Program Analyst, and Pat Hendricks, RN, CNN, QI Coordinator.
- The staff at more than 3,500 dialysis facilities in the United States who abstracted the requested information from medical records on more than 8,000 adult in-center hemodialysis, adult peritoneal dialysis, and pediatric in-center hemodialysis patients.
- 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	Kt/V or Kt/V_{urea} Urea Clearance x Time/the Volume of Distribution of Urea (fractional clearance of urea)
BCP Bromcresol Purple Laboratory Method	KUf Ultrafiltration Coefficient
BMI Body Mass Index	NIPD Nightly Intermittent Peritoneal Dialysis
BSA Body Surface Area	NKF National Kidney Foundation
BUN Blood Urea Nitrogen	PET Peritoneal Equilibration Test
CAPD Continuous Ambulatory Peritoneal Dialysis	PD Peritoneal Dialysis
CCPD Continuous Cycling Peritoneal Dialysis	QA Quality Assurance
CI Confidence Interval	QI Quality Improvement
CIP Core Indicators Project	RRF Residual Renal Function
CMS Centers for Medicare & Medicaid Services	SC Subcutaneous
CPM Clinical Performance Measure	SD Standard Deviation
CQI Continuous Quality Improvement	SI Units Systéme International Units
CrCl Creatinine Clearance	SLE Systemic Lupus Erythematosus
DM Diabetes Mellitus	spKt/V Single-Pool Kt/V
DOQI Dialysis Outcomes Quality Initiative	TCV Total Cell Volume
D/P Cr Ratio Dialysate/Plasma Creatinine Ratio	TSAT Transferrin Saturation
ESRD End-Stage Renal Disease	UKM Urea Kinetic Modeling
FSGS Focal and Segmental Glomerulosclerosis	URR Urea Reduction Ratio
GFR Glomerular Filtration Rate	USRDS United States Renal Data System
HCFA Health Care Financing Administration	VA Vascular Access
HCQIP Health Care Quality Improvement Program	
HD Hemodialysis	

I. EXECUTIVE SUMMARY

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

The 2003 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. Included again this year are the findings for all in-center hemodialysis patients aged < 18 .

The most recent data described in this report are from the 2003 study period which includes the months of October-December 2002 for the in-center hemodialysis patients and October 2002-March 2003 for the peritoneal dialysis patients. This report also compares the 2003 study period findings to findings from previous study periods AND it identifies opportunities to improve care for dialysis patients.

The full report can be found on the Internet at www.cms.hhs.gov/esrd/1.asp. Power Point 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 four major sections: **Background and Project Methods, Adult In-Center Hemodialysis Patients, Adult Peritoneal Dialysis Patients, and Pediatric In-Center Hemodialysis Patients** (aged < 18). The lists of tables and figures have been moved to the back of the report as Section VII.

This report also contains some features or tools to assist dialysis providers in using the information from this project. Appendices 8 and 9 (pages 93 and 95) contain tear out CPM Outcomes Comparison Tools (one for hemodialysis and one for peritoneal dialysis) that providers can use to record their facility-specific results for comparisons to national and network findings (network rates are only available for hemodialysis). (Note: Each provider will have to calculate its own facility-specific results to record on this tool.) Even though the national and network hemodialysis findings included in this report are from the time period October – December 2002 (national peritoneal dialysis findings are from the time period October 2002 – March 2003), your facility's 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 management 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 12, provides information on the Medicare ESRD program and why the ESRD CPM Project was initiated. Patient selection criteria and data collection and analysis methodology are also described. A short summary of each CPM collected for this project is included, with Appendix 1 providing a more detailed description of each CPM.

The **Adult In-Center Hemodialysis Patients, Adult Peritoneal Dialysis Patients** and the **Pediatric In-Center Hemodialysis Patients** sections describe the findings for each patient sample for the 2003 study period and compare these findings to previous study periods.

This report provides the dialysis community with an initial look at network and national profiles for the clinical measures that were collected for the ESRD CPM Project. Additional Supplemental Reports, describing other analyses of the data, will be prepared during 2004.

While significant improvements in care have occurred, the opportunities to improve care for dialysis patients in the U.S. in the areas of adequacy of dialysis, vascular access, and anemia management continue. Every dialysis caregiver should be familiar with the clinical practice guidelines developed by the Renal Physicians Association (1) and the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-K/DOQI) (2, 3, 4, 5). Your Network staff and Medical Review Board are also available to assist you in identifying and developing improvement efforts.

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.

ESRD CPM DATA TRENDS

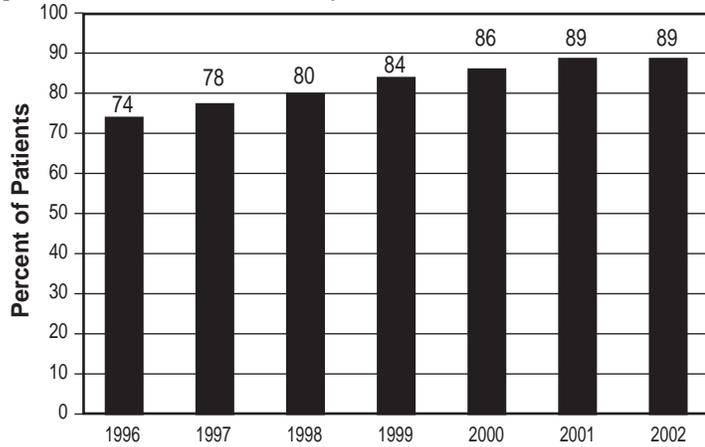
The figures on the following pages show the trends in the ESRD CPM data for various study periods.

Please note that when a single year such as 1999 is used in displaying data, it refers to October, November, and December of that year for the hemodialysis patients. When a single year 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.

NOTE: Highlights of important findings from the 2003 ESRD CPM Project may be found on the following pages:
 Adult in-center hemodialysis patients, page 9
 Adult peritoneal dialysis patients, page 10
 Pediatric in-center hemodialysis patients, page 11
 These highlights will also be on the Internet at www.cms.hhs.gov/esrd/1.asp.

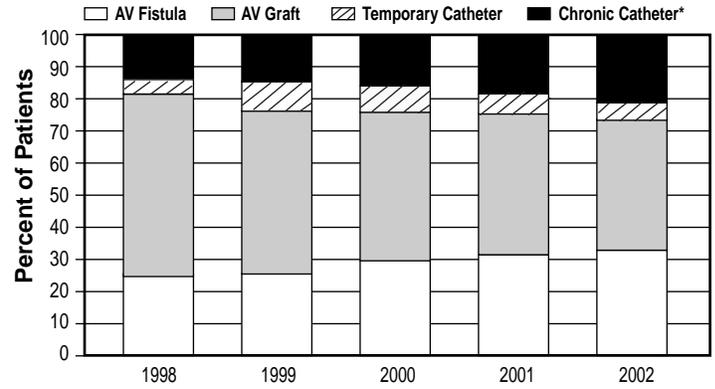
Hemodialysis Adequacy Trends

Figure 2: Percent of adult in-center hemodialysis patients with mean delivered calculated, single session single pool (sp)Kt/V ≥ 1.2 in October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



Vascular Access Trends

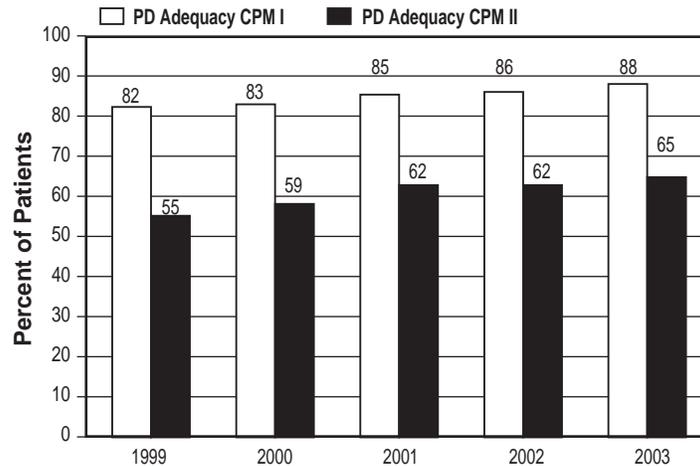
Figure 3: Vascular access type for all adult in-center hemodialysis patients on their last hemodialysis session during the study period. 2003 ESRD CPM Project.



* Chronic catheter defined as use of a catheter access continuously for 90 days or longer.

Peritoneal Dialysis Trends

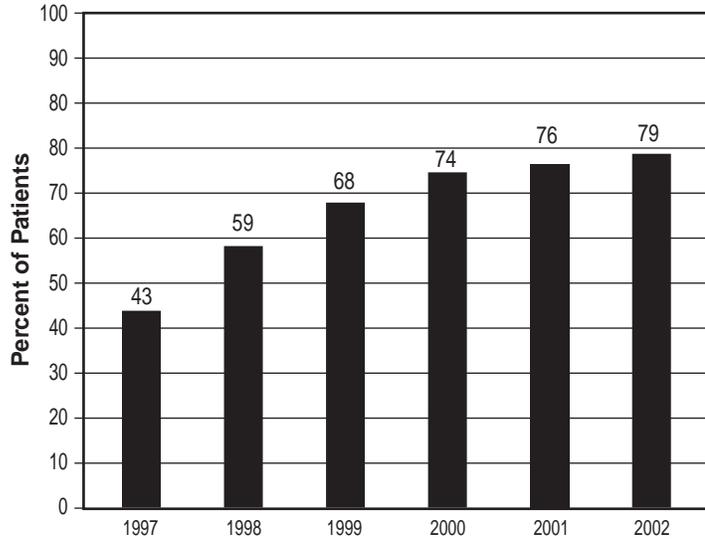
Figure 4: Percent of adult peritoneal dialysis patients with total solute clearance for urea and creatinine measured at least once during the study period (PD Adequacy CPM I) and with total solute clearance calculated in a standard way* (PD Adequacy CPM II), October 2002-March 2003 compared to previous study periods. 2003 ESRD CPM Project.



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

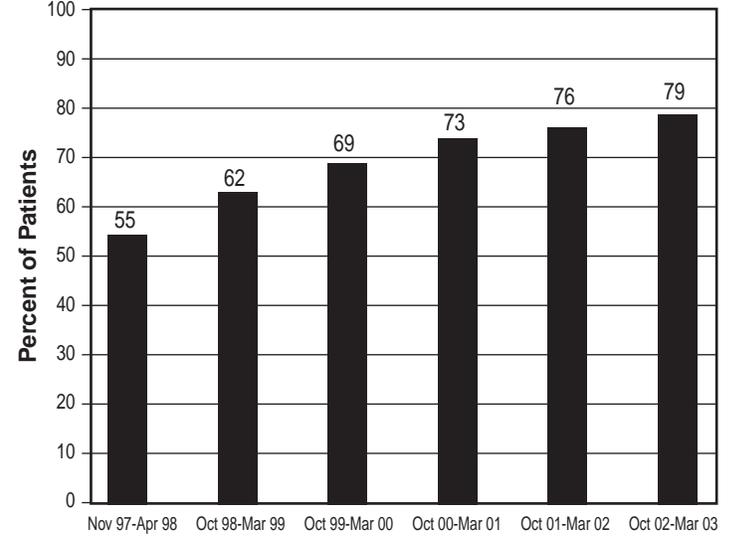
Anemia Management Trends

Figure 5: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



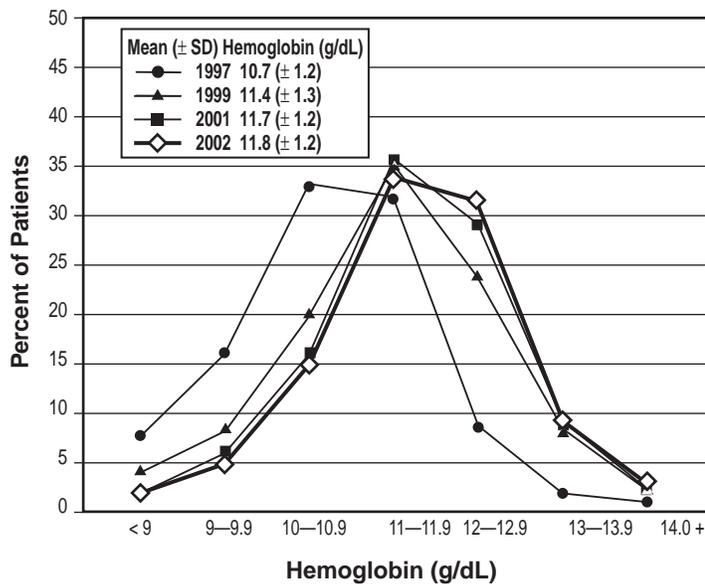
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 7: Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL, October 2002-March 2003 compared to previous study periods. 2003 ESRD CPM Project.



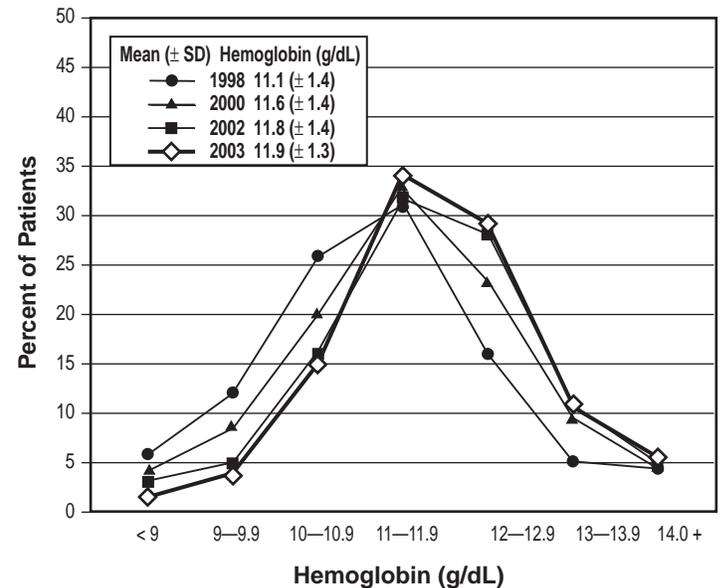
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 6: Distribution of mean hemoglobin values for adult in-center hemodialysis patients, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

Figure 8: Distribution of mean hemoglobin values for adult peritoneal dialysis patients, October 2002-March 2003 compared to previous study periods. 2003 ESRD CPM Project.



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

Pediatric Dialysis Trends

Figure 9: Distribution of mean delivered calculated, single session spKt/V values for pediatric (aged ≥ 12 to < 18 years) in-center hemodialysis patients, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.

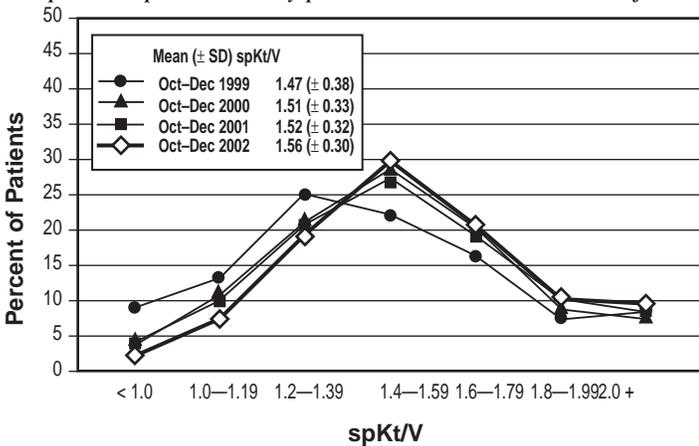
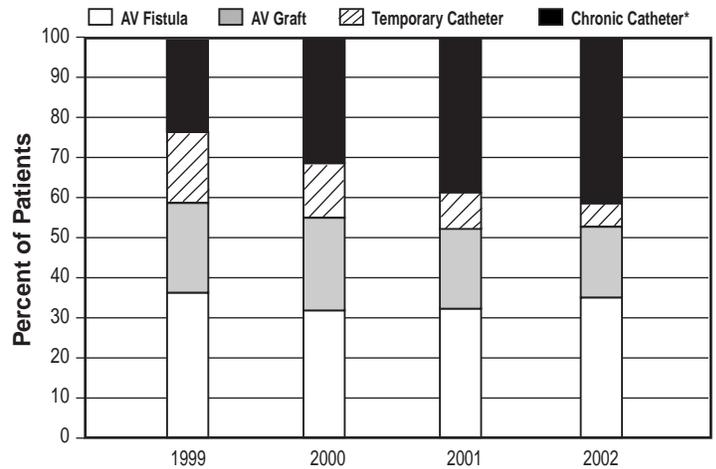
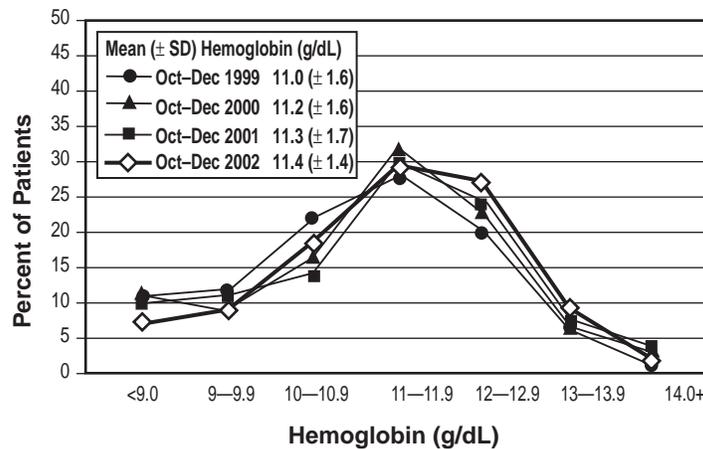


Figure 10: Vascular access type for pediatric (aged ≥ 12 to < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period. 2003 ESRD CPM Project.



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

Figure 11: Distribution of mean hemoglobin values for pediatric (aged ≥ 12 to < 18 years) in-center hemodialysis patients, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2003 ESRD CPM DATA**Random Sample Adult In-Center Hemodialysis (HD) Patients (n=8,487)**

The data are from OCT-DEC 2002:

HD Adequacy

- 83% of patients had monthly adequacy measurements performed (HD Adequacy CPM I)
- 67% of patients had their delivered spKt/V calculated using either UKM or the Daugirdas II formula (6) (HD Adequacy CPM II)
- 92% 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)
- 89% of prevalent patients had a mean delivered calculated, single session adequacy dose of spKt/V ≥ 1.2 (FIGURE 2)
- 87% of Black patients and 90% of White patients were receiving dialysis with a mean delivered calculated, single session spKt/V ≥ 1.2 in OCT-DEC 2002 (TABLE 7)
- Mean (\pm SD) spKt/V was 1.52 (\pm 0.27)
- 86% of patients had a mean URR $\geq 65\%$
- Mean (\pm SD) URR was 71.5 (\pm 7.1)%
- Mean (\pm SD) dialysis session length was 217 (\pm 30) minutes (FIGURE 19)

Opportunity to Improve Adequacy

- 11% of patients did not have a mean spKt/V ≥ 1.2 during the three-month study period

Vascular Access (VA)

- 27% of incident patients were dialyzed using an AV fistula (AVF) (VA CPM I) (FIGURE 29)
- 33% of prevalent patients were dialyzed using an AVF (VA CPM I) (FIGURE 3)
- 21% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer (VA CPM II) (FIGURE 3)
- 61% of prevalent patients with an AV graft were routinely monitored for the presence of stenosis (VA CPM III)

Opportunities to Improve Vascular Access

- 73% of incident patients and 67% of all patients were not dialyzed with an AVF during their last hemodialysis session OCT-DEC 2002
- 39% of patients with an AV graft did not have this graft routinely monitored for the presence of stenosis during the three-month study period

Anemia Management (AM)

- 36% of targeted patients prescribed Epoetin had a hemoglobin 11.0-12.0 g/dL (110-120 g/L) (AM CPM I)
- 94% of patients who met the inclusion criteria¹ had at least one documented transferrin saturation value and one documented serum ferritin concentration value (AM CPM IIa)
- 78% of patients who met the inclusion criteria¹ had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration ≥ 100 ng/mL (AM CPM IIb)
- 79% of patients who met the inclusion criteria¹ were prescribed intravenous iron in at least one month during the study period (AM CPM III)
- 79% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) in the last quarter of 2002 (FIGURE 5)
- 7% of patients had a mean hemoglobin < 10.0 g/dL (100 g/L) (FIGURE 31, TABLE 12)
- Mean (\pm SD) hemoglobin was 11.8 (\pm 1.2) g/dL (118 [\pm 12] g/L) (FIGURES 6, 31, TABLE 12)
- Mean (\pm SD) weekly IV and SC Epoetin dose was 263.7 (\pm 235.2) units/kg/week and 211.5 (\pm 231.5) units/kg/week respectively (FIGURE 38)
- 26% of patients had a mean serum ferritin > 800 ng/mL (FIGURE 39, TABLE 14)
- Mean (\pm SD) IV iron dose was 281.3 (\pm 199.8) mg/month

Opportunities to Improve Anemia Management

- 21% of patients did not have a mean hemoglobin ≥ 11 g/dL (110 g/L) during the three-month study period
- 20% of patients did not have a mean transferrin saturation $\geq 20\%$ and 8% of patients did not have a mean serum ferritin ≥ 100 ng/mL

Serum Albumin

- 35% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP)² (FIGURE 43)
- 81% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) (FIGURE 43)
- 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)

Opportunity to Improve Serum Albumin

- 65% 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

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

² BCG = bromcresol green, BCP = bromcresol purple; these are two different laboratory methods for assaying serum albumin.

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2003 ESRD CPM DATA

Random Sample of Adult Peritoneal Dialysis (PD) Patients (n=1354)

The data are from OCT 2002–MAR 2003:

PD Adequacy

- 88% 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 4)
- 65% of patients had their total solute clearance for urea and creatinine calculated in a standard way¹ (PD Adequacy CPM II) (FIGURE 4)
- 71% of CAPD patients had a mean weekly Kt/V_{urea} of ≥ 2.0 and a mean weekly creatinine clearance ≥ 60 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 (PD Adequacy CPM III) (FIGURE 50)
- 66% of Cycler patients with a daytime dwell had a mean weekly Kt/V_{urea} of ≥ 2.1 and a mean weekly creatinine clearance ≥ 63 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 (PD Adequacy CPM III) (FIGURE 50)
- 67% of Cycler patients without a daytime dwell had a mean Kt/V_{urea} of ≥ 2.2 and a mean weekly creatinine clearance ≥ 66 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 (PD Adequacy CPM III) (FIGURE 50)
- Mean weekly Kt/V_{urea} for CAPD patients was 2.30 (± 0.56)
- Mean weekly Kt/V_{urea} for Cycler patients with a daytime dwell was 2.31 (± 0.54)
- Mean weekly Kt/V_{urea} for cycler patients without a daytime dwell was 2.53 (± 0.80)

Opportunities to Improve Adequacy

- The adequacy of dialysis was not assessed during the 2003 study period for 12% of the sampled peritoneal dialysis patients
- 29% of CAPD patients did not achieve an adequate weekly Kt/V_{urea} and 36% did not achieve an adequate weekly CrCl. Likewise, 36% 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

Anemia Management (AM)

- 39% of targeted patients prescribed Epoetin had a mean hemoglobin between 11.0-12.0 g/dL (110-120 g/L) (AM CPM I)

- 77% of patients who met the inclusion criteria² had at least two documented transferrin saturation values and two documented serum ferritin concentration values during the six-month study period (AM CPM IIa)
- 81% of patients who met the inclusion criteria² had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration ≥ 100 ng/mL during the six-month study period (AM CPM IIb)
- 32% of patients who met the inclusion criteria² were prescribed intravenous iron in at least one of the two-month periods during the six-month study period (AM CPM III)
- 79% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) (FIGURE 7)
- Mean (\pm SD) hemoglobin was 11.9 (± 1.3) g/dL (119 ± 13) g/L (FIGURES 8, 51, TABLE 19)
- The mean (\pm SD) SC and IV Epoetin doses were 163.0 (± 140.9) and 208.5 (± 188.2) units/kg/week, respectively (FIGURE 53)
- 15% of patients had a mean serum ferritin > 800 ng/mL (FIGURE 54)

Opportunities to Improve Anemia Management

- 21% of patients did not have a mean hemoglobin ≥ 11 g/dL (110 g/L) in the 2003 study period
- 17% of patients did not have a mean transferrin saturation $\geq 20\%$ and 16% of patients did not have a mean serum ferritin ≥ 100 ng/mL

Serum Albumin

- 18% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP)³ (FIGURE 55)
- 60% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) (FIGURE 55)
- Mean (\pm SD) serum albumin was 3.6 (± 0.5)/3.2 (± 0.5) gm/dL (36 ± 5)/32 ± 5 g/L) (BCG/BCP)

Opportunities to Improve Serum Albumin

- 82% of PD patients did not have mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) in the 2003 study period
- 40% of PD patients did not have mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) in the 2003 study period

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 criteria.

³ BCG = bromocresol green, BCP = bromocresol purple; these are two different laboratory methods for assaying serum albumin.

Using the 1997 NKF-DOQI guidelines (13):

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

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2003 ESRD CPM DATA**100% Sample Pediatric In-Center Hemodialysis Patients (HD) (aged < 18)¹ (n=663)
The data are from OCT–DEC 2002:****Clearance**

- 90% of patients had a mean delivered calculated, single session adequacy dose of spKt/V \geq 1.2 calculated using the Daugirdas II formula (6)
- Mean (\pm SD) spKt/V was 1.57 (\pm 0.31) (FIGURE 56)
- Mean (\pm SD) dialysis session length was 204 (\pm 30) minutes

Opportunity to Improve Clearance

- 10% of patients did not have a mean spKt/V \geq 1.2 during the three-month study period

Vascular Access

- 28% of patients were dialyzed using an AV fistula (AVF) (TABLE 22)
- 47% of patients were dialyzed with a chronic catheter continuously for 90 days or longer
- 47% of patients with an AVF or an AV graft were routinely monitored for the presence of stenosis

Opportunity to Improve Vascular Access

- 53% 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

- 62% of patients had a mean hemoglobin \geq 11 g/dL (110 g/L) (FIGURE 62)
- Mean (\pm SD) hemoglobin was 11.3 (\pm 1.5) g/dL (113 [\pm 15]) g/L (FIGURE 61, TABLE 24)
- Mean (\pm SD) weekly IV Epoetin dose was 358.1 (\pm 316.6) units/kg/week
- 14% of patients had a mean serum ferritin > 800 ng/mL

Opportunity to Improve Anemia Management

- 38% of patients did not have a mean hemoglobin \geq 11 g/dL (110 g/L) during the three-month study period

Serum Albumin

- 47% of patients had a mean serum albumin \geq 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP)² (FIGURE 67)
- 84% of patients had a mean serum albumin \geq 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) (FIGURE 67)
- Mean (\pm SD) serum albumin was 3.9 (\pm 0.5)/3.7 (\pm 0.5) g/dL (39 [\pm 5]/37 [\pm 5] g/L) (BCG/BCP)

Opportunity to Improve Serum Albumin

- 53% 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 The ESRD Clinical Performance Measures (CPMs) do not apply to patients < 18 years of age.

² BCG = bromcresol green, BCP = bromcresol purple; these are two different laboratory methods for assaying serum albumin.

IMPORTANT NOTE

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

During 2004, we plan to provide a series of supplemental reports. In these reports we will provide more detailed analysis using data collected for the ESRD CPM Project as well as other data from which we can derive information about the patients in the sample identified for this project. These reports will be available at www.cms.hhs.gov/esrd/1.asp.

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.

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 334 per million population (7). As of December 31, 2002, there were 297,928 patients receiving dialysis therapy in the United States (8).

ESRD Health Care Quality Improvement Program (HCQIP)

The Centers for Medicare & Medicaid Services (CMS), which oversees the Medicare program, contracts with 18 ESRD Network Organizations throughout the United States. The ESRD Networks perform oversight activities to assure the appropriateness of services and protection for ESRD patients. In 1994, 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 (9). This approach has been 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 need and welcome both information and, where necessary, help in applying the tools and techniques of quality management (10).

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 study designed to assess and identify opportunities to improve the care of patients with ESRD (11). This project established the first consistent clinical ESRD database. The elements included in the database represent clinical measures thought to be indicative of key components of care surrounding dialysis. As such, the data points are considered "indicators" for use in triggering improvement activities. The ESRD CIP was merged with the ESRD Clinical Performance Measures Project in 1999.

ESRD Clinical Performance Measures Project

Section 4558(b) of the Balanced Budget Act (BBA) of 1997 required CMS to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, CMS funded the development of Clinical Performance Measures (CPMs) based on the National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI) Clinical Practice Guidelines (12, 13, 14, 15).

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

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 2003 ESRD CPM Project Annual Report provides the results of some of the CPMs on a sample of adult in-center hemodialysis patients and adult peritoneal dialysis patients. Findings on all pediatric (aged < 18 years) in-center hemodialysis patients are also included. The report does not provide results on a dialysis facility-specific basis. The quality of dialysis services is reported for adult and pediatric in-center hemodialysis patients for the last quarter in 2002 and adult peritoneal dialysis patients for the time period October 2002–March 2003.

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 (16). 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 (17-21).

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 (22).

This report describes the findings from the fifth data collection effort for the ESRD CPMs which was conducted in 2003 and collected data from October-December 2002 for adult and pediatric in-center hemodialysis patients, and from October 2002-March 2003 for adult peritoneal dialysis patients. These data help to determine if there are opportunities to improve care and to evaluate patterns of care across the nation.

The Sample

Annually, each ESRD Network conducts a survey of ESRD facilities to validate the census of ESRD patients in the Network at the end of the calendar year. In March 2003, a listing of adult (aged ≥ 18 years as of September 30, 2002) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 2002, 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, 2002. The final sample consisted of 8,874 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 1,436 peritoneal dialysis patients.

All pediatric (aged < 18 years) in-center hemodialysis patients in the U.S. ($n = 787$) were included in the 2003 ESRD CPM Study.

Data Collection

Two data collection forms were used: a three-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 hemodialysis facility was printed onto gummed labels, and sent to the individual ESRD Networks along with the forms to be used to collect the data. If demographic information (e.g., name, date of birth, race) or clinical information (e.g., date that initial dialysis occurred) was incorrect, facility staff were asked to correct the information on the forms. Staff at ESRD facilities were also asked to abstract ethnicity and clinical information from the medical record of each selected patient.

In May 2003, the data collection forms for patients and facilities in the sample were distributed to ESRD facilities. 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 2002. Clinical information contained in the medical record was also abstracted for each patient in the adult peritoneal dialysis sample who was receiving peritoneal dialysis at any time during the two-month periods of October–November 2002, December 2002–January 2003, and February–March 2003.

Completed forms were returned to the appropriate Network, where data were reviewed for acceptability and manually entered into the VISION software data entry program. In August 2003, each Network sent a copy of their VISION data files to CMS's contractor, Computer Sciences Corporation, where the data were aggregated and then submitted to CMS.

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.

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

C. 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 conditions of care for adult dialysis patients. These CPMs do not apply to patients under the age of 18 years. The CPMs were developed in the areas of hemodialysis and peritoneal dialysis adequacy, vascular access and anemia management. A complete description of the 13 CPMs appears in Appendix 1. The CPMs used for this report were modified slightly from the initial version for clarification and to facilitate data analysis.

The Hemodialysis Adequacy CPMs described in this report are:

- I. The patient's delivered dose of hemodialysis is measured at least once per month.
- II. The patient's delivered dose of hemodialysis reported in the patient's chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula for $spKt/V$.
- 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:

- I. The patient's total solute clearance for urea and creatinine is measured routinely (defined for this report as at least once during the six-month study period).
- II. The patient's total solute clearance for urea (weekly Kt/V_{urea}) and creatinine (weekly creatinine clearance) is calculated in a standard way. (See Peritoneal Dialysis Adequacy CPM II in Appendix 1).
- 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 63 L/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:

- 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.
- II. Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for ≥ 90 days) as their permanent chronic dialysis access.
- III. A patient's AV graft should be routinely monitored for stenosis. (See Vascular Access CPM III in Appendix 1 for a list of techniques and frequency of monitoring used to screen for the presence of stenosis).

The Anemia Management CPMs described in this report are:

- 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.
- 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.
- IIb. For all 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.
- 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 intravenous iron; UNLESS the mean transferrin saturation was $\geq 50\%$ or the mean serum ferritin concentration was > 800 ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

The clinical information collected to calculate these CPMs 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 intravenous (IV) iron are profiled.

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

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

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

D. 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 (23).

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 also defined a BCP result < 3.2 g/dL (32 g/L) as an indicator of inadequate serum albumin. Mean serum albumin values ≥ 4.0 g/dL (40 g/L) (BCG method) and ≥ 3.7 g/dL (37 g/L) (BCP method) have been defined as indicators of optimal 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 (24).

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

E. PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS

Although there are no CPMs established for the pediatric age group, demographic and clinical information from October-December 2002 were collected on all patients aged < 18 years in the U.S. in order to describe several core indicators of dialysis care. These core indicators included hemodialysis adequacy, vascular access, anemia management, and serum albumin.

F. DATA ANALYSIS

Adult In-Center Hemodialysis

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

Inclusion of a case in the analysis required that data be available for at least one of the months in the three-month project period, with at least one paired pre- and post-dialysis BUN, at least one hemoglobin, and at least one serum albumin. We were able to include for analysis 8,487 of the 8,874 patients from the sample (response rate = 96%) (TABLE 1). In the vascular access section some findings are presented for incident patients alone. Other findings in this section are presented for prevalent or all patients which include incident patients.

Characteristics regarding the gender, race, ethnicity, age, diagnosis, and duration of dialysis (years) for these patients are shown in Table 2. As expected, the characteristics of this random sample were very similar to the characteristics of the overall US hemodialysis population (7). Data regarding Epoetin use, serum ferritin concentrations, transferrin saturation levels, iron use, dialyzer KUf (ultrafiltration coefficient, the permeability of a dialyzer membrane to water), and actual time on dialysis were also analyzed. The initial analysis utilized SAS v.8.02 and Statistical Package for the Social Sciences (SPSS) software (25, 26).

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 [6]), dialysis session length, dialyzer KUf, blood pump flow rates, hemoglobin, transferrin saturation, serum ferritin concentration, prescribed Epoetin or Darbepoetin dose and serum albumin. Information on prescription and route of iron administration and dose of IV iron was collected. Because we had data

from a stratified random sample of patients (i.e., a separate random sample from each of the 18 Networks), it was necessary to weight the collected data in order to obtain unbiased estimates of mean clinical values for the total population. This weighting was done according to the proportion of each Network's total population sampled. Aggregate national results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

TABLE 1: Number of adult in-center hemodialysis patients in each Network in December 2002, sample size and response rate for the 2003 ESRD CPM Project.

Network	# HD Patients Dec 2002	Sample Size	# Acceptable Forms [^]	Response Rate %
1	9,182	487	466	95.7
2	19,831	497	467	94.0
3	11,645	491	472	96.1
4	12,636	493	438	88.8
5	16,113	495	485	98.0
6	24,861	499	482	96.6
7	15,476	495	481	97.2
8	15,145	495	488	98.6
9	18,623	496	468	94.4
10	11,312	491	453	92.3
11	16,074	495	465	93.9
12	10,013	488	455	93.2
13	11,498	491	470	95.7
14	22,394	499	491	98.4
15	11,417	491	477	97.1
16	6,558	480	471	98.1
17	13,713	494	474	96.0
18	20,666	497	484	97.4
Total	267,157	8,874	8,487	95.6

[^] 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 2002 for the following items: 1) hemoglobin; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

Two or more monthly values for these clinical measures were available for 96% of patients for hemoglobin and 96% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 90% of patients. At least one monthly paired pre- and post-dialysis BUN value was available for 100% of patients, and two or more were available for 95%. Monthly paired pre- and post-dialysis BUN values were available for 84% of patients.

TABLE 2: Characteristics of adult in-center hemodialysis patients in the 2003 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 2001.

Patient Characteristic	2003 CPM Sample for Analysis		All US in 2001*	
	# [^]	%	# in 1000s	%
TOTAL	8487	100	263.3	100
GENDER				
Men	4605	54	140.3	53
Women	3882	46	122.9	47
RACE				
American Indian/ Alaska Native	161	2	4.6	2
Asian/Pacific Islander	324	4	10.5	4
Black	3058	36	101.1	38
White	4632	55	141.6	54
Other/Unknown	312	4	5.4	2
ETHNICITY				
Hispanic	1140	13	34.1	13
Non-Hispanic	7251	85	229.2	87
Unknown	96	1	0	0
AGE GROUP (years)				
18-49	2045	24	60.9**	23
50-59	1755	21	52.2	20
60-64	859	10	29.3	11
65-69	973	11	31.7	12
70-79	1894	22	60.5	23
80+	961	11	27.4	10
CAUSE of ESRD				
Diabetes mellitus	3598	42	109.5	42
Hypertension	2234	26	72.8	28
Glomerulonephritis	938	11	29.5	11
Other/Unknown	1717	20	51.4	20
DURATION of DIALYSIS (years)				
<0.5	1030	12		
0.5-0.9	1095	13		
1.0-1.9	1587	19		
2.0-2.9	1212	14		
3.0-3.9	914	11		
4.0+	2,602	31		

*USRDS: 2003 Annual Data Report, Bethesda, MD, National Institutes of Health, 2003. Tables D.5 and D.7

[^] Subgroup totals may not equal 8,487 due to missing data.

** For ages 20-49 years

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

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 2002–March 2003. Of the 1,436 patients sampled, 1,354 patients were included in the sample for analysis (94% response rate) (TABLE 3). Selected patient characteristics of this sample for analysis are shown in Table 4.

For this report, each patient’s mean value for the six-month study period was determined from available data for the following items: weekly Kt/V_{urea}, weekly creatinine clearance, hemoglobin, serum albumin, prescribed Epoetin or Darbepoetin dose, serum ferritin concentration, and transferrin saturation level. Information on prescription, route of administration, and 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 2002, sample size and response rate for the 2003 ESRD CPM Project.

Network	# Peritoneal Dialysis Patients in December 2002	Sample Size	# Acceptable Forms [^]	Response Rate %
1	1124	70	57	81.4
2	1307	65	61	93.8
3	1091	56	53	94.6
4	885	37	26	70.3
5	1559	93	89	95.7
6	2396	148	136	91.9
7	1281	68	66	97.1
8	1613	90	90	100.0
9	2159	122	113	92.6
10	1139	61	61	100.0
11	1708	98	95	96.9
12	1269	58	57	98.3
13	1074	50	48	96.0
14	1913	101	99	98.0
15	1123	60	56	93.3
16	918	47	46	97.9
17	1559	95	89	93.7
18	1975	117	112	95.7
Total	26,093	1,436	1,354	94.3

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

TABLE 4: Characteristics of adult peritoneal dialysis patients in the 2003 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 2001.

Patient Characteristic	2003 CPM Sample for Analysis		All US in 2001*	
	# [^]	%	# in 1000s	%
TOTAL	1354	100	24.7	100
GENDER				
Men	719	53	12.6	51
Women	635	47	12.1	49
RACE				
American Indian/ Alaska Native	17	1	0.4	1.6
Asian/Pacific Islander	86	6	1.3	5
Black	361	27	6.4	26
White	846	62	16.1	65
Other/Unknown	44	3	0.5	2
ETHNICITY				
Hispanic	157	12	3.0	12
Non-Hispanic	1180	87	21.8	88
Other/Unknown	17	1	0 ^{**}	0
AGE GROUP (years)				
18-49	513	38	8.5	34
50-59	308	23	5.6	23
60-64	152	11	2.5	10
65-69	126	9	2.5	10
70-79	202	15	3.7	15
80+	53	4	1.0	4
CAUSE of ESRD				
Diabetes mellitus	471	35	8.6	35
Hypertension	297	22	5.4	22
Glomerulonephritis	230	17	4.6	19
Other/Unknown	356	26	6.1	25
DURATION of DIALYSIS (years)				
<0.5	177	13		
0.5-0.9	226	17		
1.0-1.9	322	24		
2.0+	191	14		
3.0-3.9	124	9		
4.0	313	23		

*USRDS: 2003 Annual Data Report, Bethesda, MD, National Institutes of Health, 2003. Tables D.5 and D.7.

[^] Subgroup totals may not equal 1354 due to missing data.

** For ages 20-49 years

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

Pediatric In-Center Hemodialysis Patients

Inclusion of a case 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 787 patients, 663 patients were included in the sample for analysis (84% response rate). Selected patient characteristics of this sample for analysis are shown in Table 5.

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

G. REPORT FORMAT

This report describes the clinical performance measures and other findings for both the in-center hemodialysis patient sample and the peritoneal dialysis patient sample in separate sections, III and IV, respectively, for the following study periods: October–December 2002 for the adult in-center hemodialysis patients, and October 2002–March 2003 for the adult peritoneal dialysis patients. This report also describes findings on clinical parameters of care for pediatric in-center hemodialysis patients in the U.S. for October–December 2002 in Section V.

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 2003 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 2003 ESRD CPM Project.

Patient Characteristic	2003 CPM Project	
	# [^]	%
TOTAL	663	(100)
GENDER		
Males	367	(55)
Females	296	(45)
RACE		
American Indian/ Alaska Native	11	(2)
Asian/Pacific Islander	25	(4)
Black	240	(36)
White	321	(48)
Other/Unknown	66	(10)
ETHNICITY		
Hispanic	180	(27)
Non-Hispanic	472	(71)
Other/Unknown	11	(2)
AGE GROUP (years)		
0-4	27	(4)
5-9	73	(11)
10-14	242	(37)
15 to <18	321	(48)
CAUSE of ESRD		
Congenital/Urologic	187	(28)
FSGS	98	(15)
Glomerulonephritis	91	(14)
Cystic Disease	29	(4)
SLE	26	(4)
Hypertension	17	(3)
Other/Unknown	215	(32)
DURATION of DIALYSIS (years)		
<0.5	113	(17)
0.5-0.9	129	(19)
1.0-1.9	129	(19)
2.0-2.9	62	(9)
3.0-3.9	44	(7)
4.0+	173	(26)

[^]Subgroup totals may not equal 663 due to missing data.

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 2002 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 94% of patients for hemoglobin and 94% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 86% of patients. At least one monthly paired pre- and post-dialysis BUN value was available for 100% of patients, and two or more were available for 92%. Monthly paired pre- and post-dialysis BUN values were available for 78% of patients.

III. 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 2002 (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 2002; and
- (3) a comparison of CPM and/or other quality indicators results or findings for October–December 2002 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, 2002, was selected ($n=8874$). 8487 patients (96%) were included in the sample for analysis.

A. ADEQUACY OF HEMODIALYSIS

1. CPM Findings for October–December 2002

Data to assess three hemodialysis adequacy CPMs were collected in 2003. The time period from which these data were abstracted was October–December 2002. 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 2002). These measurements were recorded in the patient's chart, not calculated from individual data points. An additional 11% 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) (6).

FINDING: 67% 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 (6). This CPM is calculated on the subset of patients who had been on hemodialysis for six months or longer and who were dialyzing three times per week ($n=6511$).

FINDING: For the last quarter of 2002, 92% of the adult in-center hemodialysis patients who met the inclusion criteria (only those patients who had been on hemodialysis for six months or longer and who were dialyzing three times per week [$n=6511$]) 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 2002

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 0.4% ($n=38$) 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 2002 was 1.52 (± 0.27). The distribution of spKt/V values for these patients is shown in Figure 12. The mean (\pm SD) delivered calculated URR for this sample was 71.5 (± 7.1)%. 86% 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 6.

The percent of patients in the sample for analysis with at least one calculated spKt/V measure available ($n=8348$) 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 2002 was 89% (TABLE 6, FIGURE 2).

The percent of patients receiving hemodialysis with a mean delivered spKt/V ≥ 1.2 was higher for women than for men, higher for Whites than for Blacks, 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 6).

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 94% vs. 78% respectively) (TABLE 6).

Figure 12: Distribution of mean delivered calculated, single session spKt/V values for adult in-center hemodialysis patients, October–December 2002. 2003 ESRD CPM Project.

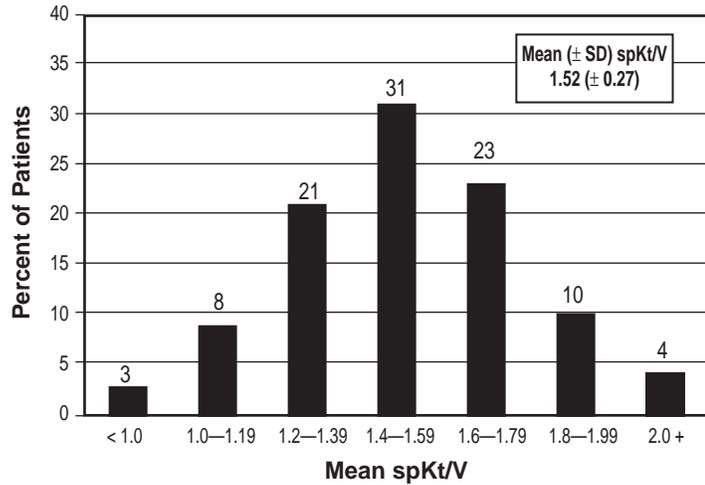
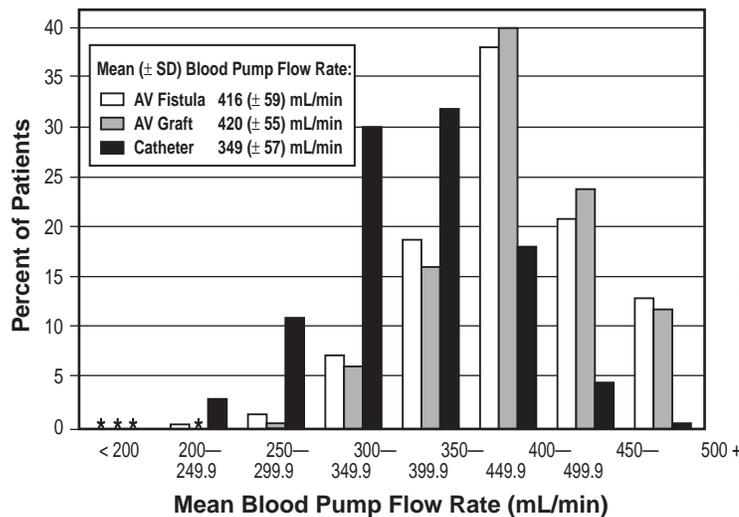


Figure 13: Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for adult in-center hemodialysis patients, by access type, October–December 2002. 2003 ESRD CPM Project.



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).

*Value suppressed because n ≤ 10.

TABLE 6: Mean delivered calculated, single session spKt/V and percent of adult in-center hemodialysis patients with mean delivered calculated, single session spKt/V ≥ 1.2 and ≥ 1.3 by patient characteristics, October-December 2002. 2003 ESRD CPM Project.

Patient Characteristics	Mean spKt/V	spKt/V ≥ 1.2%	spKt/V ≥ 1.3%
TOTAL	1.52	89	81
GENDER			
Men	1.45	85	75
Women	1.60	93	88
RACE			
American Indian/ Alaska Native	1.61	92	86
Asian/Pacific Islander	1.60	93	86
Black	1.48	87	78
White	1.54	90	82
Other/Unknown	1.52	89	83
ETHNICITY			
Hispanic	1.57	90	84
Non-Hispanic	1.51	89	80
AGE GROUP (years)			
18-44	1.48	85	76
45-54	1.48	85	76
55-64	1.51	89	80
65-74	1.54	91	84
75+	1.57	94	87
CAUSE of ESRD			
Diabetes mellitus	1.51	88	80
Hypertension	1.52	90	81
Glomerulonephritis	1.52	90	81
Other/Unknown	1.53	89	82
DURATION of DIALYSIS (years)			
< 0.5	1.37	70	58
0.5-0.9	1.48	86	75
1.0-1.9	1.51	90	81
2.0-2.9	1.55	93	86
3.0-3.9	1.55	92	86
4.0+	1.58	94	87
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)			
32.4-59.2	1.69	97	94
59.3-68.1	1.58	94	88
68.2-77.3	1.52	91	83
77.4-90.2	1.45	86	77
90.3-215.6	1.36	77	63
ACCESS TYPE			
AV Fistula	1.52	92	83
AV Graft	1.58	94	88
Catheter	1.42	78	67
MEAN Hgb (g/dL)			
≥ 11	1.53	91	83
< 11	1.49	83	74
MEAN SERUM ALBUMIN (g/dL)			
≥ 3.5/3.2 BCG/BCP*	1.53	90	82
< 3.5/3.2 BCG/BCP	1.49	84	75

* 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 (\pm SD) dialysis session length was 217 (\pm 30) minutes. The mean dialysis session length was somewhat longer for men than for women (224 minutes vs. 209 minutes), for Blacks than for Whites (222 minutes vs. 215 minutes), and for patients dialyzing six months or longer compared to patients dialyzing less than six months (218 minutes vs. 211 minutes). Patients in the highest quintile of post-dialysis body weight (kg) had longer dialysis session lengths compared to patients in the lowest quintile (236 minutes vs. 199 minutes). The mean dialysis session length was 220 minutes for patients dialyzed with an AVF, 215 minutes for patients with either a synthetic or bovine graft, and 216 minutes for patients with a catheter access during October-December 2002.

The mean (\pm SD) delivered blood pump flow rate 60 minutes into the dialysis session was 416 (\pm 59) mL/min for patients with an AVF, 420 (\pm 55) mL/min for patients with either a synthetic or bovine graft, and 349 (\pm 57) mL/min for patients with a catheter access during October -December 2002 (FIGURE 13). Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood 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).

The percent of patients who received adequate hemodialysis varied significantly from one geographic region to another. Table 7 shows, by gender, race, and ethnicity, the percent of patients who received hemodialysis with a mean delivered spKt/V \geq 1.2 in each Network area. The percent of all patients with mean delivered spKt/V \geq 1.2 ranged from 84% to 94% among the 18 Networks (FIGURES 14, 15).

Figure 14: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V \geq 1.2, by Network, October–December 2002. 2003 ESRD CPM Project.

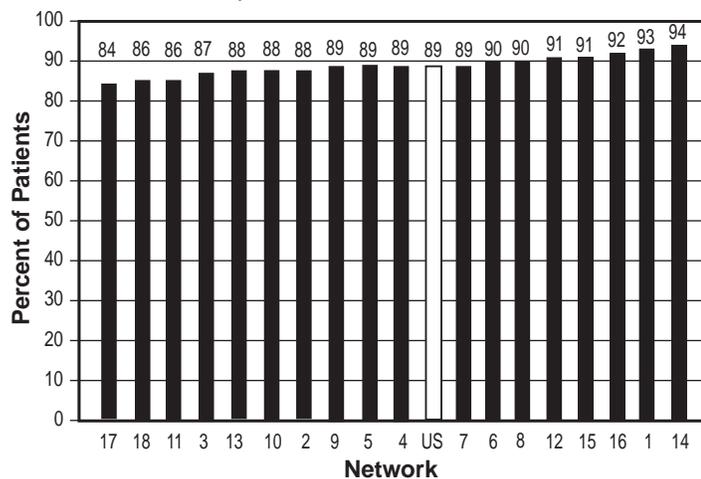
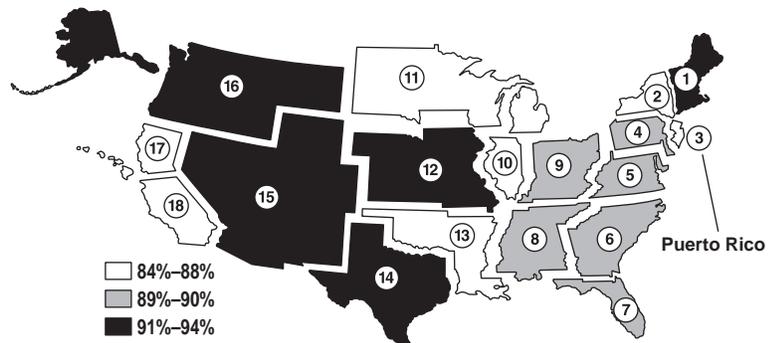


Figure 15: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKt/V \geq 1.2, by Network, October–December 2002. 2003 ESRD CPM Project.



3. CPM and other Findings for October-December 2002 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 (\pm SD) delivered spKt/V in October-December 2002 was 1.52 (\pm 0.27), an increase from previous study years. The percent of patients receiving dialysis with a mean delivered spKt/V \geq 1.2 increased significantly from 86% in late 2000 to 89% in late 2002 (FIGURE 2). This significant improvement occurred for both men and women and for White and Black patients (FIGURES 16, 17).

Figure 16: Percent of adult male in-center hemodialysis patients with mean delivered, single session spKt/V \geq 1.2, by race, October–December 2002 compared to previous study periods. 2003 ESRD CPM Project.

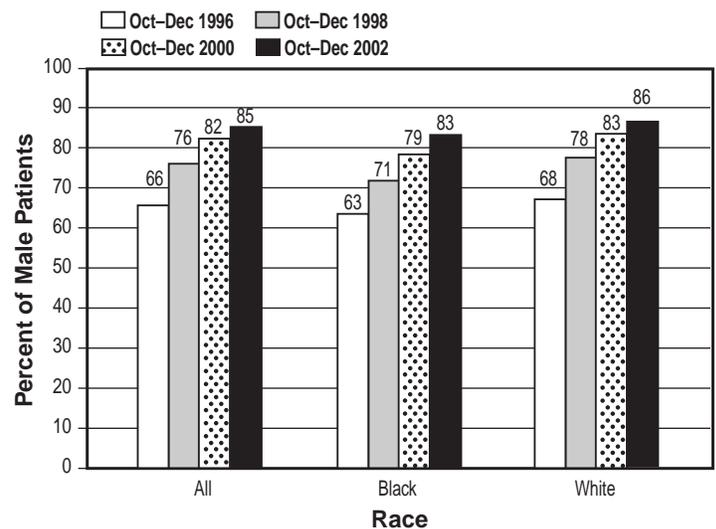


TABLE 7: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session spKtV \geq 1.2, by gender, race, ethnicity, and Network, October-December 2002. 2003 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	93	88	87	89	89	90	89	90	89	88	86	91	88	94	91	92	84	86	89	
GENDER																				
Men	90	85	86	86	83	85	86	87	85	83	80	87	84	90	89	90	77	85	85	
Women	96	92	88	94	96	95	94	95	92	94	94	95	91	98	93	95	92	88	93	
RACE																				
Black	89	87	85	87	87	90	89	90	87	88	84	88	86	93	83	94	75	77	87	
White	93	90	87	90	93	88	89	91	90	88	88	92	90	94	91	91	83	87	90	
ETHNICITY																				
Hispanic	96	81	87	*	93	*	94	*	*	89	85	100	85	93	94	97	88	88	90	
Non-Hispanic	93	90	87	89	89	90	88	90	88	88	87	90	88	94	90	91	83	85	89	

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

* Value suppressed because $n \leq 10$.

Figure 17: Percent of adult female in-center hemodialysis patients with mean delivered, single session $spKt/V \geq 1.2$, by race, October–December 2002 compared to previous study periods. 2003 ESRD CPM Project.

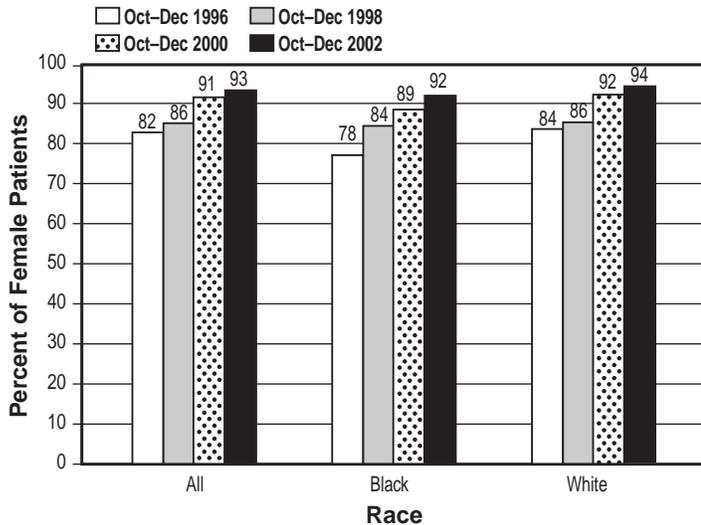
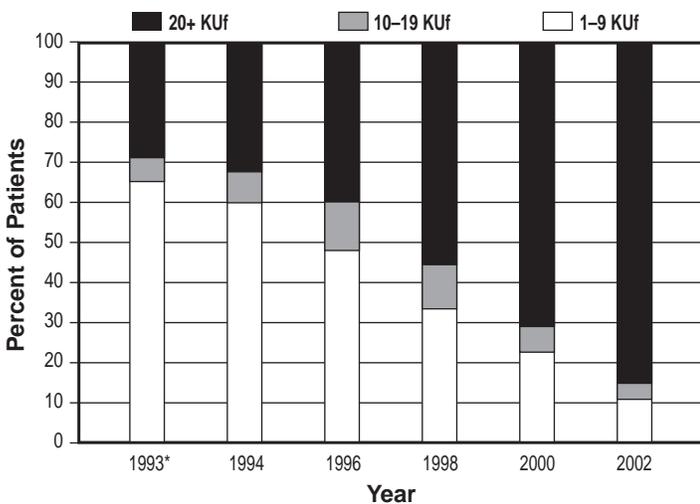


Figure 18 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category October–December 2002, compared to previous study years. The percent of patients dialyzed with a dialyzer with a KUF ≥ 20 mL/mmHg/hr increased from approximately 30% in late 1993 to approximately 85% in late 2002.

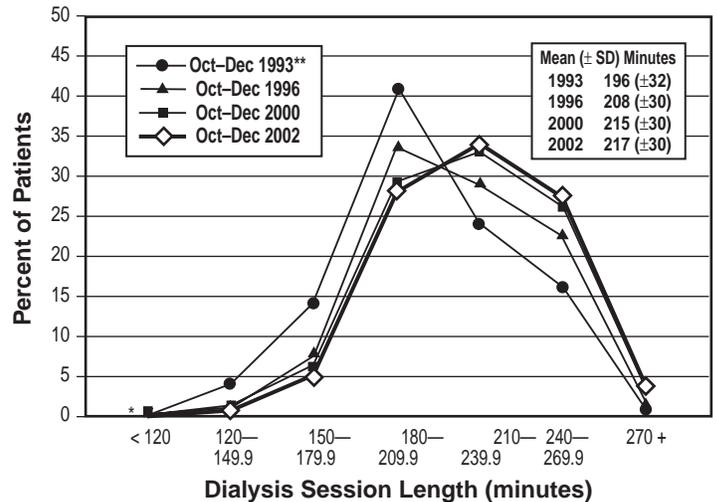
Figure 18: Percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category, October–December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

Figure 19 shows a trend for slight increases in dialysis session lengths from late 1993 to late 2002.

Figure 19: Distribution of mean dialysis session length (minutes), October–December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

B. VASCULAR ACCESS

1. CPM Findings for October–December 2002

Data to assess three vascular access CPMs were collected in 2003. The time period from which these data were abstracted was October–December 2002. 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: 27% of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 2002 and August 31, 2002, [n = 1491]) were dialyzed using an AVF on their last hemodialysis session during October–December 2002 (TABLE 8).

33% of all patients in the sample for analysis were dialyzed using an AVF during their last hemodialysis session October–December 2002 (TABLE 8).

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

FINDING: 21% of all patients in the sample for analysis were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 2002 (FIGURE 20).

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: 61% of patients with an AV graft (n=3329) had this graft routinely monitored for the presence of stenosis during October–December 2002.

TABLE 8: Vascular access type for incident[^] and all adult in-center hemodialysis patients during the last hemodialysis session of the study period, by selected patient characteristics, October-December 2002. 2003 ESRD CPM Project.

Patient Characteristic	Incident (n=1491)			Prevalent (n=8487)		
	AVF %	Graft %	Catheter %	AVF %	Graft %	Catheter %
TOTAL	27	32	41	33	41	27
GENDER						
Men	35	27	38	42	34	24
Women	19	38	44	22	48	30
RACE						
American Indian/ Alaska Native	*	*	*	40	42	17
Asian/Pacific Islander	33	37	30	35	44	21
Black	23	38	39	29	46	25
White	30	29	41	35	37	28
Other/Unknown	*	26	58	35	37	28
ETHNICITY						
Hispanic	30	33	38	38	41	22
Non-Hispanic	27	32	41	32	41	27
AGE GROUP (years)						
18-44	33	21	46	42	32	26
45-54	29	32	39	38	38	25
55-64	30	34	36	32	44	24
65-74	28	34	38	28	45	27
75+	21	35	44	27	42	31
CAUSE of ESRD						
Diabetes Mellitus	26	34	40	29	43	28
Hypertension	27	35	39	33	43	24
Glomerulonephritis	39	24	38	41	35	24
Other/Unknown	27	28	45	35	36	30
DURATION of DIALYSIS (years)						
< 0.5	22	28	51	16	22	63
0.5-0.9	29	34	37	29	33	37
1.0-1.9	N/A	N/A	N/A	37	39	23
2.0-2.9	N/A	N/A	N/A	35	44	20
3.0-3.9	N/A	N/A	N/A	38	45	17
4.0+	N/A	N/A	N/A	35	49	16

[^]An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2002 and August 31, 2002.

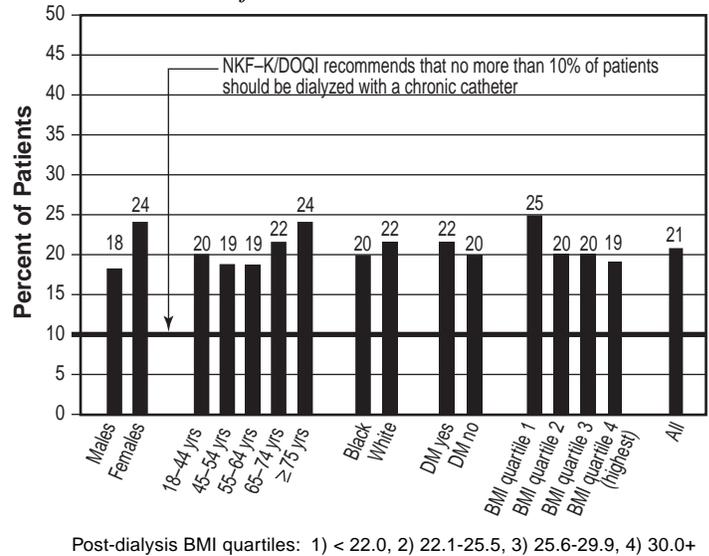
Note: Percentages may not add up to 100% due to rounding.

*Value suppressed because n ≤ 10.

2. Other Vascular Access Findings for October-December 2002

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

Figure 20: 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 2002, by patient characteristics. 2003 ESRD CPM Project.



betes mellitus, and patients dialyzing six months or longer were more likely to be dialyzed with an AVF compared to women, Blacks, non-Hispanics, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLE 8). With the exception of males, American Indians/Alaska Natives, and patients 18-44 years old, all patient groups examined were below the current NKF-K/DOQI recommendation of 40% of prevalent patients having an AVF as their vascular access (4) (TABLE 8, FIGURE 21). The percent of prevalent patients with a catheter as their vascular access, by several patient characteristics, is shown in Table 8 and Figure 22. More women, Whites, patients ≥ 75 years old, and patients in the lowest quartile of post-dialysis BMI had a catheter access compared to men, Blacks, younger patients, and patients in higher quartiles of post-dialysis BMI (FIGURE 22).

More women and patients in the lowest quartile of post-dialysis BMI were dialyzed with a chronic catheter compared to men and patients in higher quartiles of post-dialysis BMI (FIGURE 20). 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 25% to 46% among the 18 Network areas (FIGURE 23, TABLE 9). This geographic variation in AVF use was also noted for incident patients, ranging from 17% to 45% among the 18 Network areas (FIGURE 24).

The percent of patients dialyzed with a catheter exhibited geographic variation, ranging from 17% to 33% among the 18 Network areas (FIGURE 25, TABLE 10). Chronic catheter use was 21% nationally, and ranged from 11% to 28% across the 18 Network areas (FIGURE 26).

Figure 21: 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 2002, by patient characteristics. 2003 ESRD CPM Project.

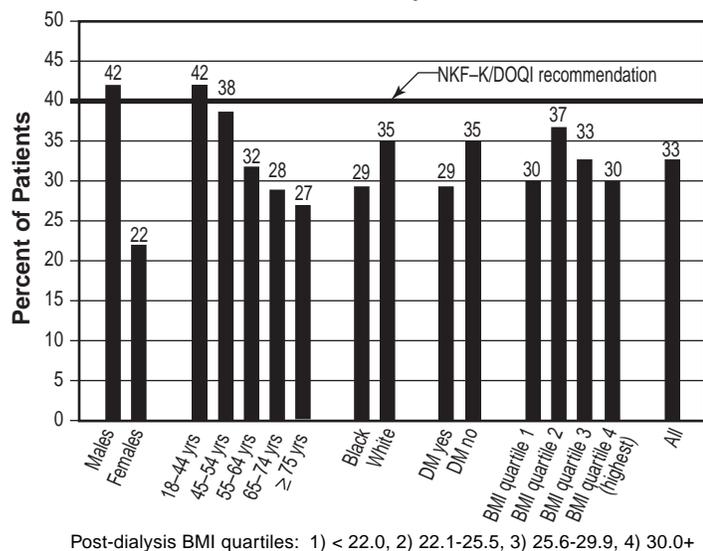


Figure 22: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October-December 2002, by patient characteristics. 2003 ESRD CPM Project.

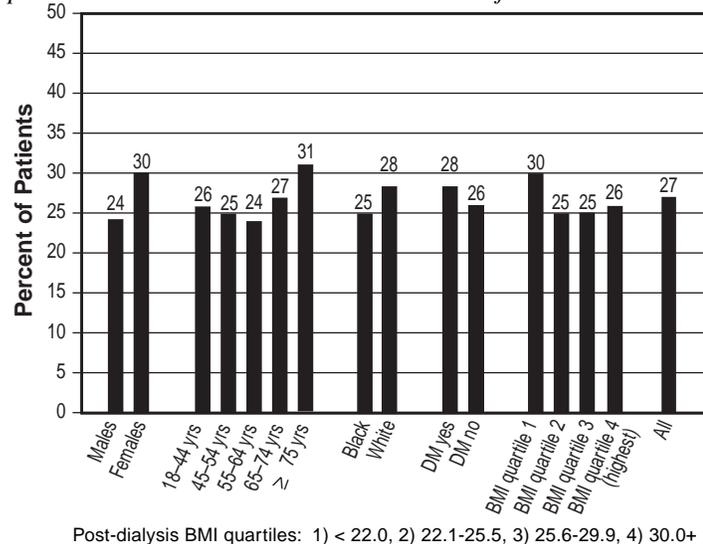


Figure 23: Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2002, by Network. 2003 ESRD CPM Project.

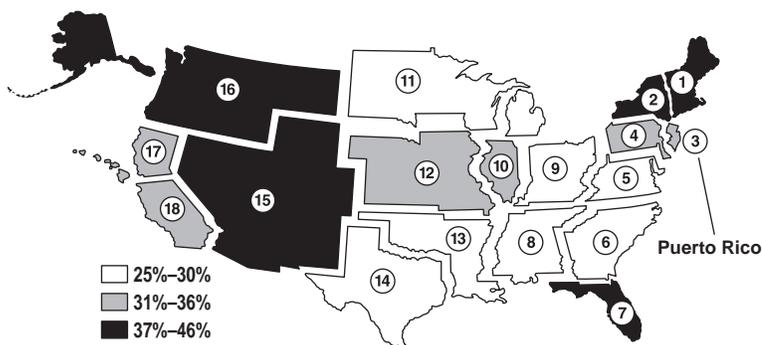
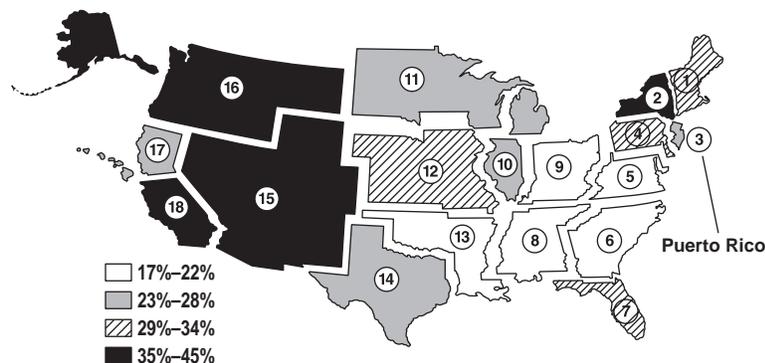


Figure 24: Percent of incident* adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October-December 2002, by Network. 2003 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2002 and August 31, 2002.

Figure 25: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October-December 2002, by Network. 2003 ESRD CPM Project.

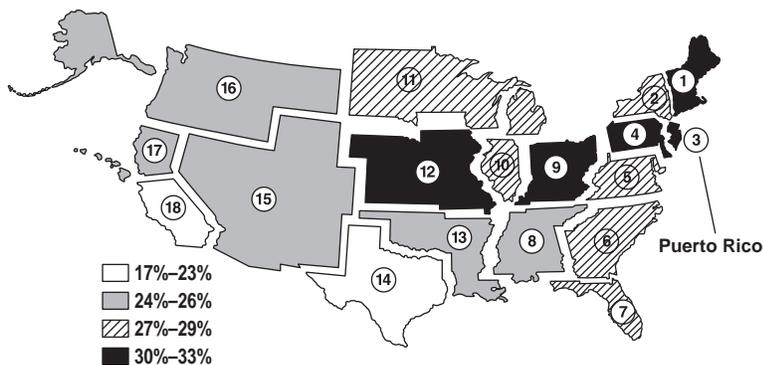


Figure 26: Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October-December 2002, by Network. 2003 ESRD CPM Project.

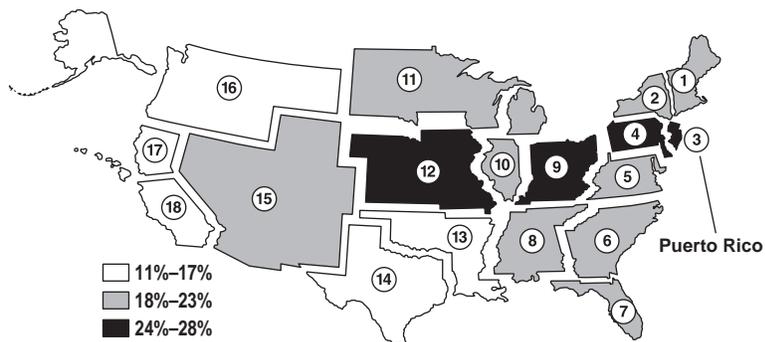


TABLE 9: Percent of all adult in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 2002, by gender, race, ethnicity, age, cause of ESRD, and Network. 2003 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	44	41	36	31	28	28	37	27	30	31	30	33	25	26	38	46	33	36	33
GENDER																			
Men	60	52	43	38	37	38	46	33	39	40	40	44	36	34	49	52	46	45	42
Women	26	27	24	21	17	19	24	18	19	21	18	23	13	18	25	38	18	28	22
RACE																			
Black	38	39	34	22	27	28	37	27	25	28	24	29	26	22	*	31	27	33	29
White	44	42	37	37	30	29	37	27	33	35	33	35	22	28	41	47	33	38	35
ETHNICITY																			
Hispanic	40	46	42	*	*	*	35	*	*	35	*	*	*	28	44	59	41	40	38
Non-Hispanic	44	40	33	32	28	28	37	27	30	31	30	33	25	25	35	45	31	33	32
AGE GROUP (years)																			
18-44	58	48	50	33	33	41	42	42	46	25	42	53	33	37	47	46	34	48	42
45-54	56	52	43	43	35	34	32	30	32	38	31	37	32	33	38	55	33	44	38
55-64	42	38	36	29	26	21	46	31	27	31	30	28	26	27	38	62	43	26	32
65-74	33	36	28	26	23	25	40	15	28	35	30	25	23	20	32	36	32	26	28
75+	42	33	29	27	25	21	28	16	23	27	23	33	*	17	35	37	22	41	27
CAUSE OF ESRD																			
Diabetes Mellitus	39	36	32	28	23	24	34	24	27	31	28	26	23	23	34	41	34	32	29
Other Causes Combined	48	43	39	33	31	31	38	29	32	32	32	38	26	30	42	50	32	39	35

* Value suppressed because n ≤ 10.

TABLE 10: Percent of all adult in-center hemodialysis patients with a catheter access on their last hemodialysis session during October–December 2002, by gender, race, ethnicity, age, cause of ESRD, and Network. 2003 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	30	27	32	32	28	27	28	25	33	29	29	30	26	17	24	24	25	21	27	
GENDER																				
Men	19	25	28	29	25	25	24	23	31	26	25	25	23	16	22	23	21	19	24	
Women	42	29	38	36	33	30	34	29	36	31	33	36	30	18	26	25	29	22	30	
RACE																				
Black	28	24	25	32	29	26	23	22	32	28	25	27	22	16	35	*	25	19	25	
White	30	27	36	32	27	33	33	30	34	31	31	33	31	18	25	24	26	21	28	
ETHNICITY																				
Hispanic	32	28	29	*	*	*	35	*	*	30	*	*	*	15	20	*	25	19	22	
Non-Hispanic	30	26	33	32	29	28	27	25	34	28	29	31	26	18	26	24	24	23	27	
AGE GROUP (years)																				
18-44	26	29	26	37	40	21	28	18	28	41	30	27	23	18	23	30	26	18	26	
45-54	23	21	30	30	26	27	27	25	30	30	26	27	20	17	26	21	27	20	25	
55-64	32	28	28	32	33	27	21	22	35	22	21	28	28	14	21	*	19	18	24	
65-74	34	19	38	30	20	30	24	29	40	23	29	33	25	16	30	29	26	24	27	
75+	30	37	36	32	25	32	38	33	33	31	35	34	36	22	20	24	25	23	31	
CAUSE OF ESRD																				
Diabetes Mellitus	31	27	35	29	28	36	28	27	36	25	30	31	24	18	25	26	22	23	28	
Other Causes Combined	29	27	30	33	29	22	28	24	32	31	28	30	27	16	23	22	26	19	26	

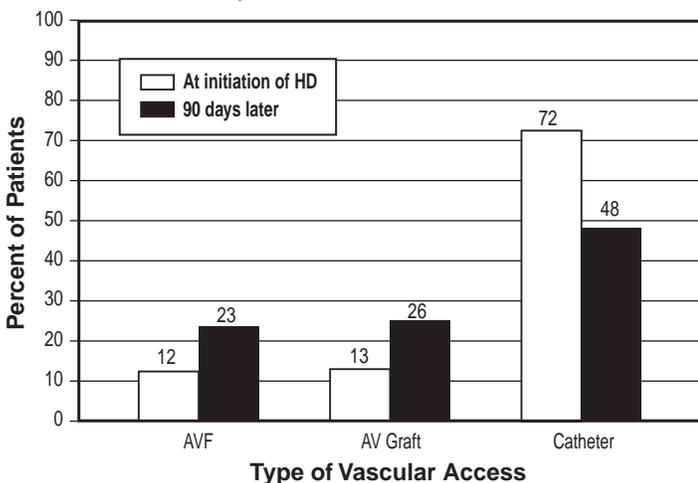
* Value suppressed because n ≤ 10.

27% (n=2266) of all patients in the sample for analysis were dialyzed with a catheter during their last hemodialysis session of the study period (TABLES 8, 10). The most common reasons for catheter placement were: the fistula or graft was maturing, not ready to cannulate (27%), no fistula or graft surgically planned (22%) and no fistula or graft surgically created at this time (18%) (TABLE 11). 12% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

58% of patients with an AVF or AV graft (n=6132) had their vascular access monitored for stenosis during the study period. For this subset of patients, 61% were monitored with dynamic venous pressure, 13% with static venous pressure, 9% with the dilution technique, 4% with Color-flow Doppler, and 21% with "Other" techniques (groups not mutually exclusive).

12% of incident patients had an AVF as their vascular access upon initiation of a maintenance course of hemodialysis; 23% of incident patients had an AVF as their vascular access 90 days later (FIGURE 27). 72% of incident patients had a catheter as their vascular access upon initiation of a maintenance course of hemodialysis; 48% of incident patients had a catheter as their vascular access 90 days later (FIGURE 27).

Figure 27: 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. 2003 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2002 and August 31, 2002.

TABLE 11: Reasons for catheter placement in adult in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2002. 2003 ESRD CPM Project.

Reason	n	(%)
TOTAL	2266	(100)
Fistula or graft maturing, not ready to cannulate	618	(27)
No fistula or graft surgically planned	502	(22)
Patient preference	307	
Peripheral vascular disease	163	
Physician preference	46	
Patient size too small for AV fistula/graft	33	
Renal transplantation scheduled	16	
No fistula or graft surgically created at this time	406	(18)
Temporary interruption of fistula or graft use due to clotting, revision, or other reasons	315	(14)
All fistula or graft sites have been exhausted	279	(12)
Other	146	(6)

*Note: Subtotals may not add up to 2266 as respondents could choose multiple reasons. Percents may not add up to 100% due to rounding.

3. CPM and other Findings for October-December 2002 compared to previous study periods.

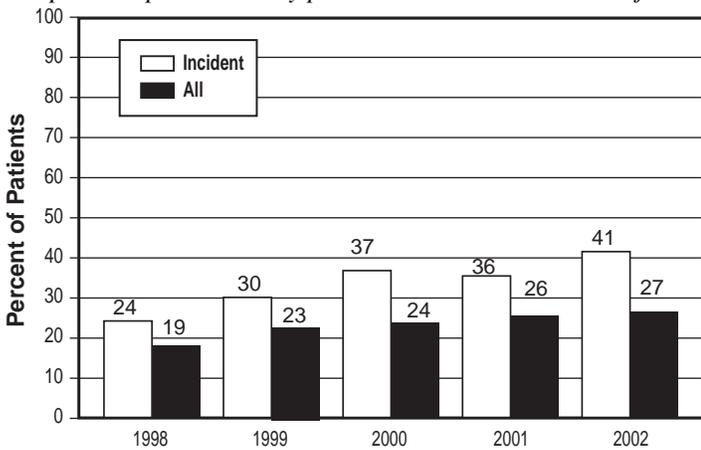
More patients were dialyzed with a catheter on their last hemodialysis session during October-December 2002 compared to October-December 1998, 1999, 2000, and 2001 (27% compared to 19%, 23%, 24% and 26%, respectively) (FIGURES 3, 28). A similar pattern was noted for incident patients, with 41% of incident patients in late 2002 dialyzed with a catheter on their last hemodialysis session compared to 24% in late 1998, 30% in late 1999, 37% in late 2000, and 36% in late 2001. (FIGURE 28).

There was some change in the percent of all patients dialyzed with an AVF on their last hemodialysis session from late 1998 to late 2002 (26% vs. 33%, respectively) (FIGURE 29). 26% of incident patients were dialyzed with an AVF on their last hemodialysis session in late 1998 compared to 27% in late 2002 (FIGURE 29).

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 2002 (FIGURE 3).

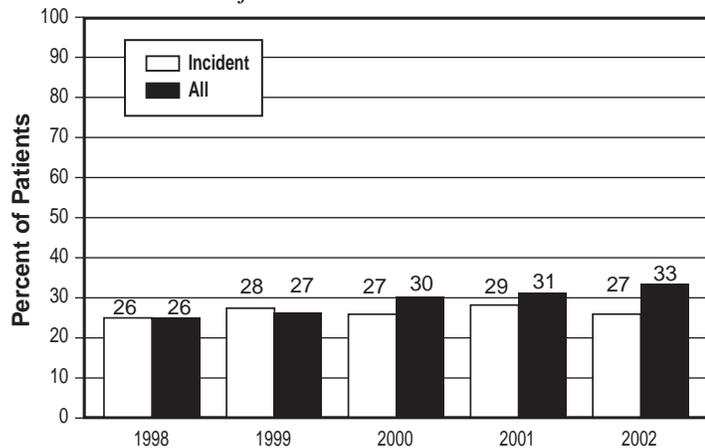
There was a 5% increase in the percent of dynamic venous pressure monitoring for patients with either an AVF or an AV graft as their vascular access from late 2001 to late 2002 (FIGURE 30).

Figure 28: 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 2002 compared to previous study periods. 2003 ESRD CPM Project.



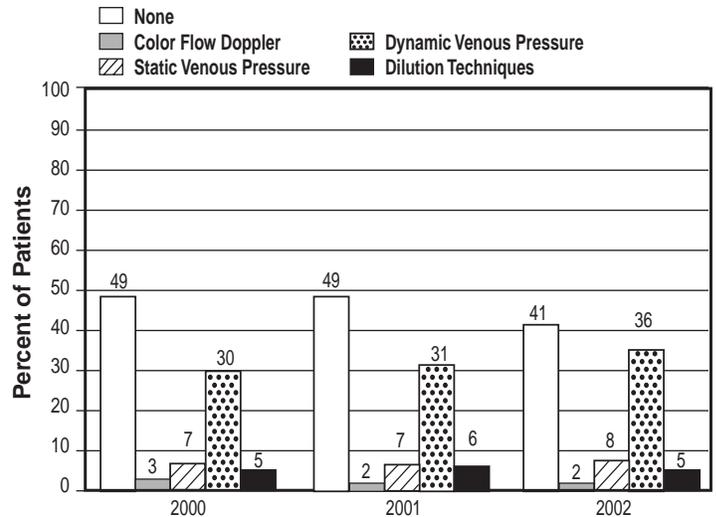
*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, of the study year.

Figure 29: 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 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

Figure 30: Types of stenosis monitoring reported for adult in-center hemodialysis patients with either an AV fistula or an AV graft as their vascular access on their last hemodialysis session during October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

C. ANEMIA MANAGEMENT

1. CPM Findings for October–December 2002

Data were collected to assess three anemia management CPMs. The time period from which these data were abstracted was October–December 2002.

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 2002, 36% of the in-center hemodialysis patients who met the inclusion criteria (n=8263) had a mean hemoglobin 11–12 g/dL (110–120 g/L).

Anemia Management CPM Ila — For all anemic patients (hemoglobin < 11 g/dL [110 g/L]) or patients prescribed Epoetin, the percent transferrin saturation and the serum ferritin concentration are assessed (measured) at least once in a three-month period.

FINDING: For the last quarter of 2002, 94% of the in-center hemodialysis patients who met the inclusion criteria (n=8230) 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 2002, 78% of the in-center hemodialysis patients who met the inclusion criteria (n=8230) had at least one documented transferrin saturation ≥ 20% and at least one documented serum ferritin concentration ≥ 100 ng/mL during the study period.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 g/dL [110 g/L]), or patients prescribed Epoetin, and with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was ≥ 50% or the mean serum ferritin concentration was ≥ 800 ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

FINDING: 79% of the in-center hemodialysis patients who met the inclusion criteria (n=2666) were prescribed intravenous iron in at least one month during October–December 2002.

2. Other Anemia Management Findings for October–December 2002

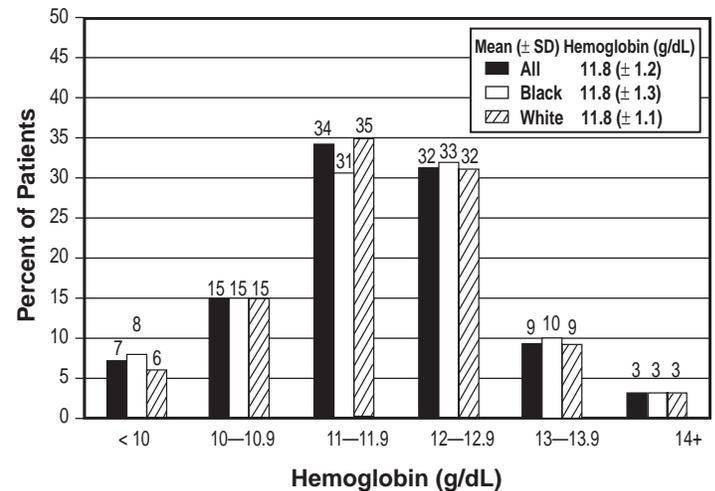
NOTE: The following findings apply to all the adult in-center hemodialysis patients in the sample for analysis regardless of when they first initiated dialysis.

The distributions of mean hemoglobin values are shown in Figure 31 for both Black and White patients. The mean (± SD) hemoglobin value for all patients in this sample was 11.8 (± 1.2) g/dL (118 [±12] g/L). The mean hemoglobin values for gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters are shown in Table 12.

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

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

Figure 31: Distribution of mean hemoglobin values for adult in-center hemodialysis patients in the US, by race, October–December 2002. 2003 ESRD CPM Project.



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

TABLE 12: Mean hemoglobin values (g/dL) for adult in-center hemodialysis patients in the US, by patient characteristics, October–December 2002. 2003 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	11.8	7	15	34	32	9	3
GENDER							
Men	11.8	6	14	32	33	10	4
Women	11.7	7	16	36	31	8	2
RACE							
American Indian/ Alaska Native	11.9	*	17	29	34	12	*
Asian/Pacific Islander	11.8	7	12	37	31	10	*
Black	11.8	8	15	31	33	10	3
White	11.8	6	15	35	32	9	3
Other/Unknown	11.8	7	11	39	30	9	*
ETHNICITY							
Hispanic	11.9	5	12	38	32	10	3
Non-Hispanic	11.8	7	15	33	32	9	3
AGE GROUP (years)							
18-44	11.7	9	15	33	30	10	4
45-54	11.8	7	15	33	31	9	5
55-64	11.8	7	15	34	32	10	3
65-74	11.7	7	15	34	33	8	2
75+	11.8	4	14	35	35	9	2
CAUSE of ESRD							
Diabetes mellitus	11.8	6	15	35	32	9	3
Hypertension	11.8	7	15	33	33	9	3
Glomerulonephritis	11.8	6	15	35	31	9	4
Other/Unknown	11.7	8	15	33	31	9	4
DURATION of DIALYSIS (years)							
< 0.5	11.3	21	20	27	21	9	3
0.5-0.9	12.0	5	11	27	39	14	4
1.0-1.9	11.9	5	13	35	35	9	3
2.0-2.9	11.8	4	14	36	36	7	2
3.0-3.9	11.8	5	13	40	32	8	2
4.0+	11.8	5	16	36	31	9	3
MEAN spKt/V							
≥ 1.2	11.8	5	14	35	33	9	3
< 1.2	11.5	15	18	28	25	10	4
MEAN SERUM ALBUMIN (g/dL)							
≥ 3.5/3.2 BCG/BCP [^]	11.9	4	13	35	35	10	3
< 3.5/3.2 BCG/BCP	11.3	17	22	31	22	6	2
ACCESS TYPE							
AVF	11.9	4	13	35	34	10	3
AV Graft	11.8	5	15	34	34	9	3
Catheter	11.5	12	17	32	27	9	3

* Value suppressed because n ≤ 10.

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

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

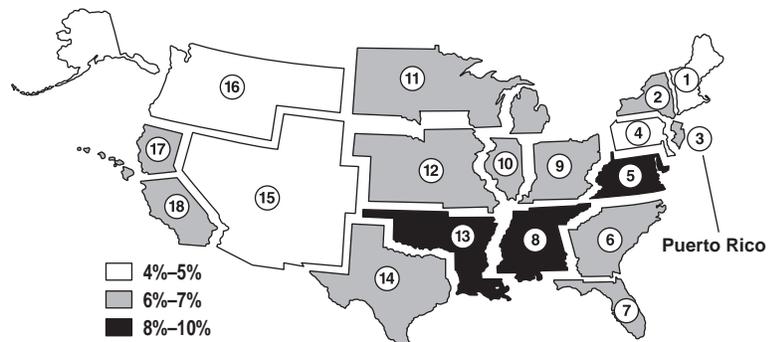
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

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 (100 g/L) was higher in patients dialyzing less than 6 months compared to those dialyzing 6 months or longer, higher in patients 18-44 years of age compared to older patients, higher in non-Hispanics compared to Hispanics, and, as reported previously, higher in Blacks than in Whites (29).

A higher proportion of patients with a mean spKt/V < 1.2 compared to patients with higher mean spKt/V values had a mean hemoglobin value <10 g/dL (100g/L) . A higher proportion of patients dialyzed with a catheter had a mean hemoglobin < 10 g/dL (100 g/L) compared to patients dialyzed with either an AVF or an AV graft. A higher proportion of patients with a mean serum albumin < 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) compared to patients with higher mean serum albumin values had a mean hemoglobin < 10 g/dL (100 g/L) (TABLE 12). The prevalence of patients with mean hemoglobin < 10 g/dL (100g/L) ranged from 4% to 10% among Networks (FIGURE 32).

Figure 32: Percent of adult in-center hemodialysis patients with mean hemoglobin < 10 g/dL, by Network, October–December 2002. 2003 ESRD CPM Project.



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

The percent of all patients with mean hemoglobin ≥ 11 g/dL (110 g/L) was 79% nationally and ranged from 74% to 82% by Network (TABLE 13, 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 (81% vs. 60%, respectively). A higher percent of patients dialyzed with an AVF or an AV graft met this threshold compared to patients dialyzed with a catheter (83% and 80% compared to 71%, respectively). Patients with higher mean spKt/V and serum albumin values were more likely to meet this hemoglobin target than patients with lower spKt/Vs and serum albumin values.

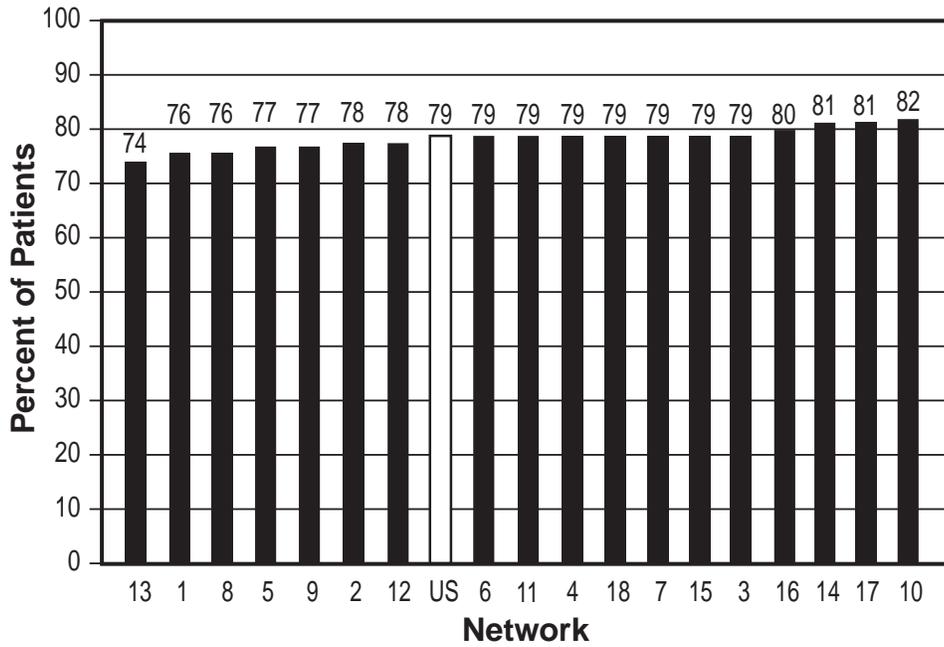
TABLE 13: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by gender, race, ethnicity, age, and Network, October-December 2002. 2003 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	76	78	79	79	77	79	79	76	77	82	79	78	74	81	79	80	81	79	79
GENDER																			
Men	78	76	82	77	78	83	80	77	77	82	79	77	79	80	84	80	83	82	80
Women	73	80	75	82	75	75	78	75	77	81	78	79	69	82	74	79	78	76	77
RACE																			
Black	75	77	81	81	74	81	78	76	73	82	77	75	72	76	77	83	86	73	77
White	75	78	79	79	79	74	79	76	79	80	81	79	77	83	77	81	79	80	79
ETHNICITY																			
Hispanic	77	86	79	*	93	*	86	*	*	91	92	92	*	84	82	81	79	83	83
Non-Hispanic	75	76	79	80	76	79	78	76	77	81	80	77	75	78	78	79	81	77	78
AGE GROUP (years)																			
18-44	68	80	70	69	67	79	74	76	78	83	78	72	75	84	73	77	73	75	76
45-54	73	74	76	79	81	80	79	84	77	79	79	78	66	76	84	76	80	76	78
55-64	72	79	82	81	72	83	76	78	77	80	79	78	70	79	83	77	88	80	79
65-74	78	79	79	81	79	74	81	70	73	81	78	76	81	82	77	82	77	78	78
75+	81	78	85	81	85	77	83	71	80	87	80	83	78	87	78	84	85	86	82

*Value suppressed because $n \leq 10$.

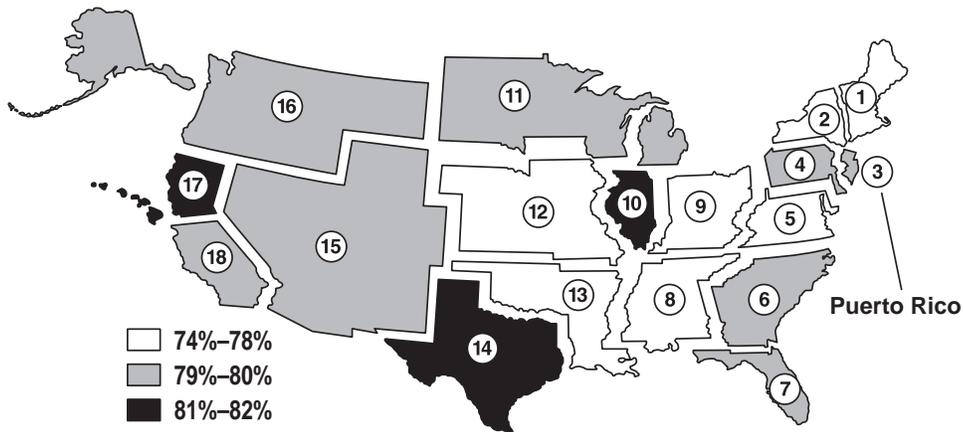
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 33: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by Network, October–December 2002. 2003 ESRD CPM Project.



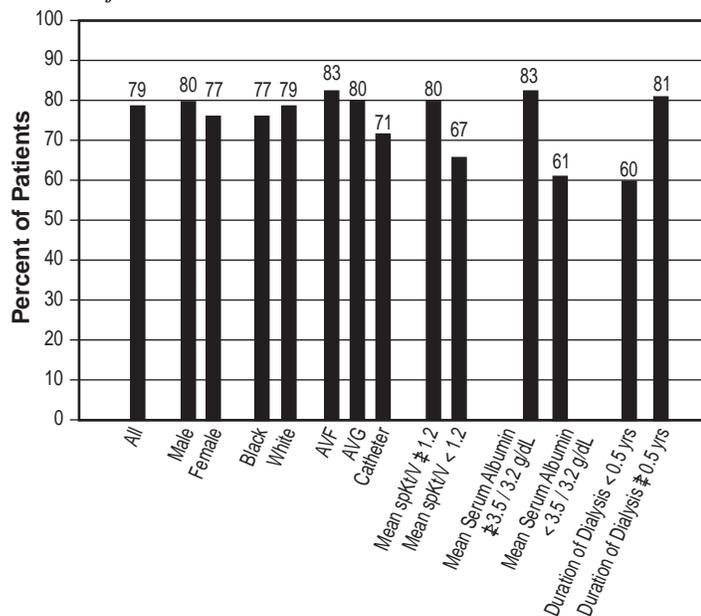
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

Figure 34: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by Network, October–December 2002. 2003 ESRD CPM Project.



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

Figure 35: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 g/dL, by selected patient characteristics and clinical parameters, October-December 2002. 2003 ESRD CPM Project.



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

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

The national average (\pm SD) transferrin saturation for the patients in the sample was 29.8 (\pm 12.9)% and ranged from 27.6% to 32.0% among the 18 Network areas (TABLE 14). Table 14 also provides the percent of patients with mean transferrin saturation $\geq 20\%$ nationally (80%) and by Network area, ranging from 73% to 86%.

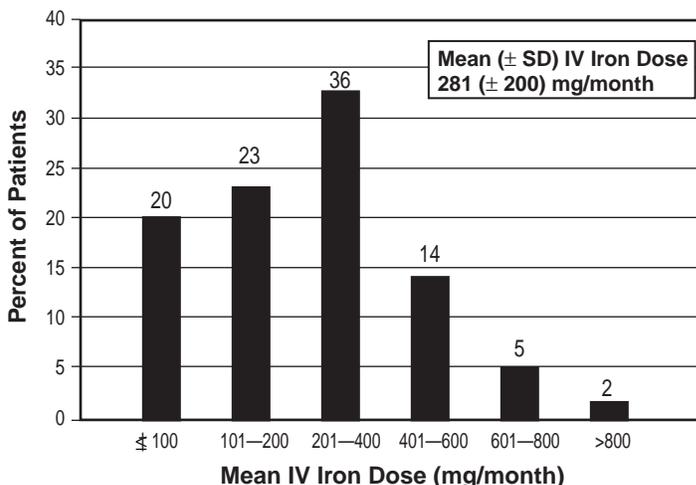
The national average (\pm SD) serum ferritin concentration for the patients in the sample was 599 (\pm 430)ng/mL and ranged from 514 to 687 ng/mL among the 18 Network areas. The percent of patients with a mean serum ferritin concentration ≥ 100 ng/mL nationally was 92%, ranging from 90% to 95% among the 18 Network areas (TABLE 14).

66% of patients were prescribed either intravenous (IV) or oral iron at least once during the three-month study period. The percent of patients with IV iron prescribed nationally was 64%, ranging from 57% to 70% among the 18 Network areas (TABLE 14).

For the subset of patients with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL (n=266 or 3% of patients), only 72% were prescribed IV iron at least once during the three-month study period.

The mean administered IV iron dose was 281 (\pm 200) 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 2002. 2003 ESRD CPM Project.



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

96% of all patients were prescribed Epoetin, of which 93% were prescribed Epoetin by the IV route; and 8% 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 (15), ranged from 2% to 18% among the 18 Network areas (TABLE 14). The mean (\pm SD) weekly Epoetin dose was 263.7 (\pm 235.2) units/kg/week by the IV route, and 211.5 (\pm 231.5) units/kg/week by the SC route.

53 patients in the sample for analysis were prescribed Darbepoetin at least once during the three-month study period.

TABLE 14: Regional variation for various anemia management measures for adult in-center hemodialysis patients including the percent of patients with mean hemoglobin ≥ 11 g/dL, mean hemoglobin (g/dL), and mean serum albumin ≥ 4.0 BCG[^] for these patients nationally and by Network, October-December 2002. 2003 ESRD CPM Project.

ANEMIA MANAGEMENT MEASURE:	NETWORK																		US
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	
Percent of patients with mean hemoglobin ≥ 11 g/dL	76	78	79	79	77	79	79	76	77	82	79	78	74	81	79	80	81	79	79
Mean hemoglobin (g/dL)	11.6	11.7	11.8	11.7	11.8	11.8	11.7	11.7	11.8	12.0	11.8	11.6	11.7	11.9	11.9	11.9	11.8	11.8	11.8
Percent of patients with mean serum albumin ≥ 4.0 g/dL BCG [^]	32	40	33	34	36	34	33	34	28	39	30	27	36	35	36	26	35	32	34
Average transferrin saturation (TSAT) (%)	28.9	30.9	30.0	29.8	30.6	32.0	30.9	28.6	29.0	29.2	28.9	28.7	29.3	29.8	29.1	27.6	29.0	30.1	29.8
Percent of patients with mean TSAT $\geq 20\%$	78	80	79	77	83	86	83	76	77	79	79	74	79	85	80	73	79	81	80
Average serum ferritin concentration (ng/mL)	587	611	537	584	562	613	687	612	655	653	554	577	647	646	546	514	542	559	599
Percent of patients with mean serum ferritin concentration ≥ 100 ng/mL	90	91	90	91	92	93	94	95	95	94	91	91	92	93	92	92	92	93	92
Percent of patients with mean serum ferritin concentration > 800 ng/mL	25	27	19	24	23	27	34	28	30	31	23	23	30	28	22	21	21	24	26
Percent of patients with IV iron prescribed	62	62	67	65	67	59	63	66	70	64	64	63	64	62	67	68	64	57	64
Mean IV iron dose (mg/month)	284	285	272	305	283	296	294	312	278	309	287	269	291	291	229	233	254	253	281
Percent of patients prescribed Epoetin	97	97	97	97	98	97	98	95	95	96	96	96	96	93	95	95	96	95	96
Percent of patients * with subcutaneous Epoetin prescribed	4	5	11	3	2	6	4	5	10	13	8	16	6	11	3	15	5	18	8
Percent of patients with mean hemoglobin < 11 g/dL with Epoetin prescribed	99	99	96	98	98	96	98	94	92	95	98	94	94	93	97	96	96	99	96

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

*Among patients prescribed Epoetin

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

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

3. CPM and other Findings for October-December 2002 compared to previous study periods

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

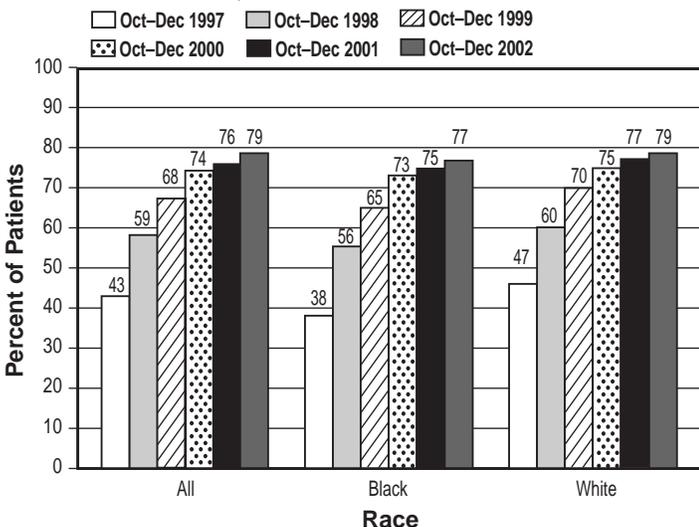
The mean hemoglobin (\pm SD) from October–December 2001 to October–December 2002 increased from 11.7 (\pm 1.2) g/dL (117 [\pm 12] g/L) to 11.8 (\pm 1.2) g/dL (118 [\pm 12] g/L) (FIGURE 6), and the percent of patients with a mean hemoglobin \geq 11 g/dL (110 g/L) increased significantly from 76% to 79% (FIGURES 5, 37).

In addition to the improvement in the percent of patients with mean hemoglobin \geq 11 g/dL (110 g/L), there was also a decrease in the percent of patients with mean hemoglobin $<$ 10 g/dL (100 g/L). In October–December 2001, 9% of Black patients and 7% of White patients had a mean hemoglobin $<$ 10 g/dL (100 g/L), while in October–December 2002, 8% of Black patients and 6% 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 2002. SC Epoetin doses were systematically lower than IV Epoetin doses at all hemoglobin categories examined. Of the patients prescribed Epoetin, 8% of patients were prescribed SC Epoetin in late 2002, a slight change from late 2001.

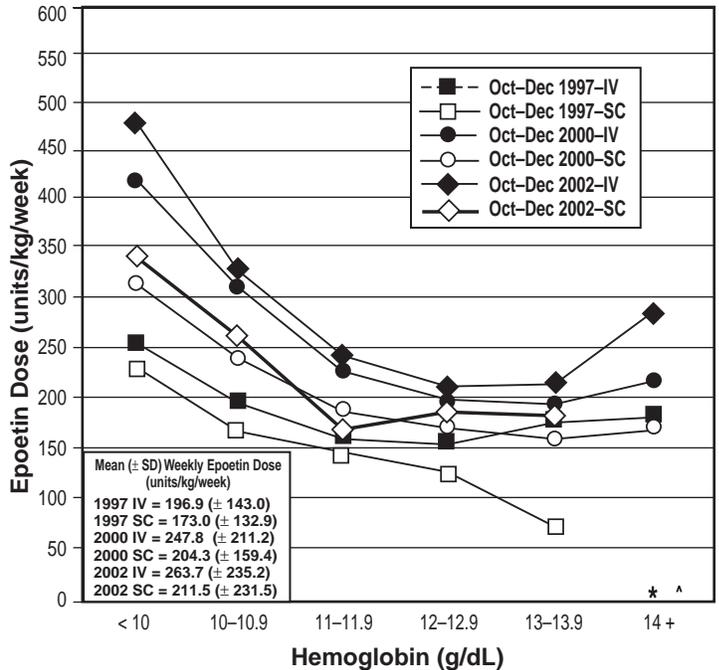
Figure 39 depicts the status of iron stores for the sampled patients in late 2002 compared to selected previous study periods. 64% of patients were prescribed IV iron in late 2002 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation $<$ 20% and mean serum ferritin concentration $<$ 100 ng/mL, 72% of patients were prescribed IV iron at least once over the three-month study period in late 2002, compared to 37% in late 1996.

Figure 37: Percent of adult in-center hemodialysis patients with mean hemoglobin values \geq 11 g/dL, by race, October–December 2002 compared to previous study periods. 2003 ESRD CPM Project.



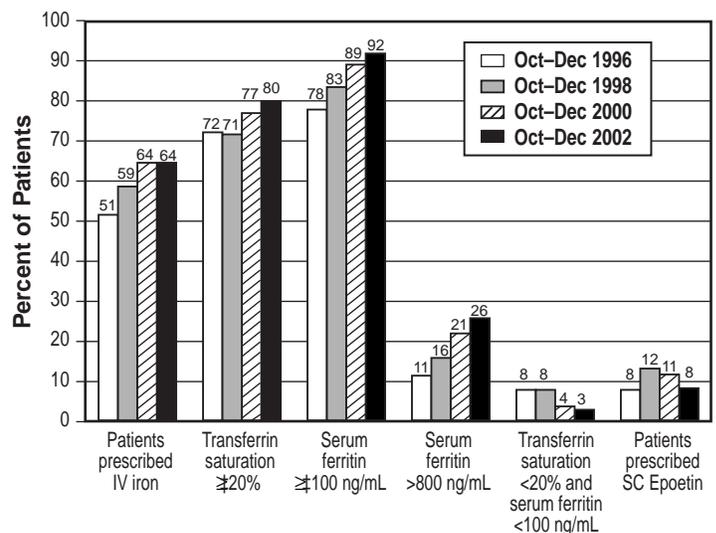
Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

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 2002 compared to selected previous study periods. 2003 ESRD CPM Project.



Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.
 *Value suppressed because n \leq 10.
 ^Value suppressed due to low number of patients in cell (n = 17).

Figure 39: Percent of adult in-center hemodialysis patients with specific anemia management indicators, October–December 2002 compared to selected previous study periods. 2003 ESRD CPM Project.



D. SERUM ALBUMIN

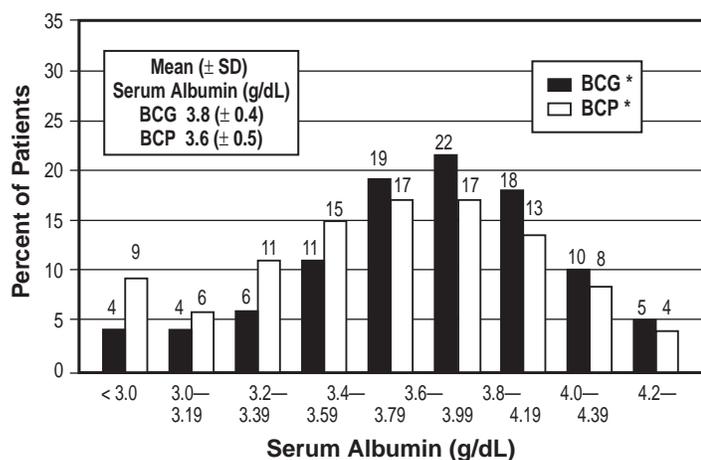
1. Findings for October–December 2002

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 (23). Therefore, we assessed the serum albumin values reported for these two methods separately. The mean (\pm SD) serum albumin value for patients whose value was determined by the BCG method (n=7574) was 3.8 (\pm 0.4) g/dL (38 [\pm 4] g/L), and by the BCP method (n=909) was 3.6 (\pm 0.5) g/dL (36 [\pm 5] g/dL) (FIGURE 40).

Mean serum albumin values $<$ 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) are defined as inadequate and have been shown to be markers for diminished survival (30-32). Figure 40 displays the distribution of serum albumin values by laboratory method.

The percents of patients with mean serum albumin \geq 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) and \geq 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) by gender, race, ethnicity, age, diagnosis groups, duration of dialysis, and selected clinical parameters are shown in Table 15. A higher percent of men, Blacks, Hispanics, patients 18-44 years old, patients with causes of ESRD other than diabetes mellitus, and patients dialyzing six months or longer had a mean serum albumin \geq 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) compared to women, Whites, non-Hispanics, patients older than 44 years, patients with diabetes mellitus as the cause of ESRD, and patients dialyzing less than six months (TABLES 15, 16, FIGURES 41, 42). Only 16% of patients dialyzing less than six months achieved an "optimal" serum albumin compared to 38% of patients dialyzing six months or more.

Figure 40: Distribution of mean serum albumin for adult in-center hemodialysis patients, by laboratory method, October–December 2002. 2003 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 15: Percent of adult in-center hemodialysis patients with mean serum albumin values \geq 4.0/3.7 g/dL (BCG/BCP)* and \geq 3.5/3.2 g/dL (BCG/BCP) in the US, by patient characteristics, October-December 2002. 2003 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin \geq 4.0/3.7 g/dL	Percent of Patients with Mean Serum Albumin \geq 3.5/3.2 g/dL
TOTAL	35	81
GENDER		
Men	41	84
Women	29	78
RACE		
American Indian/ Alaska Native	24	75
Asian/Pacific Islander	42	85
Black	40	83
White	32	79
Other/Unknown	41	84
ETHNICITY		
Hispanic	39	84
Non-Hispanic	35	80
AGE GROUP (years)		
18-44	52	87
45-54	42	83
55-64	33	81
65-74	31	79
75+	24	76
CAUSE of ESRD		
Diabetes mellitus	28	77
Hypertension	41	84
Glomerulonephritis	45	87
Other/Unknown	39	82
DURATION of DIALYSIS (years)		
< 0.5	16	58
0.5-0.9	31	79
1.0-1.9	34	83
2.0-2.9	41	85
3.0-3.9	41	86
4.0+	41	86
MEAN spKt/V		
\geq 1.2	36	82
< 1.2	30	73
MEAN Hgb (g/dL)		
\geq 11	38	85
< 11	25	65
ACCESS TYPE		
AVF	43	88
4.4+ AF Graft	37	84
Catheter	24	69

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

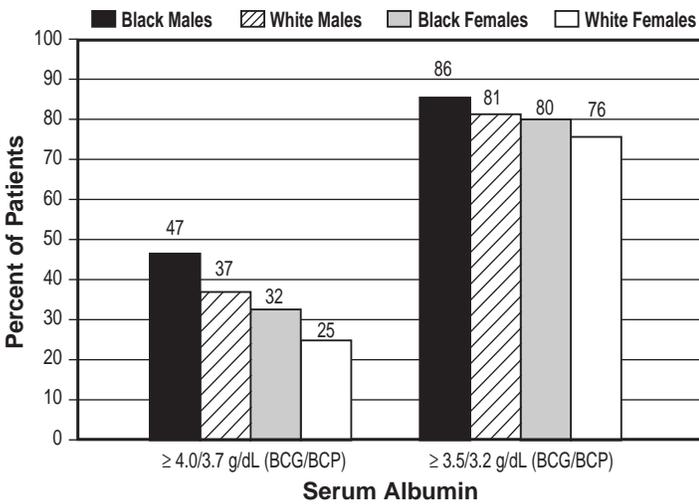
Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

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

Patients with higher mean hemoglobin and mean spKt/V values had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) compared to patients with lower mean hemoglobin and mean spKt/V values. More patients dialyzed with either an AVF or an AV graft compared to patients dialyzed with a catheter had a mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) (43% and 37% vs. 24% respectively) (TABLE 15).

Nationally, 35% of patients had mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) ranging from 25% to 45% among the 18 Networks; 81% of patients had mean serum albumin $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) ranging from 75% to 84% among the 18 Networks. The percent of patients in each Network area, by gender, race, ethnicity, age group and cause of ESRD, with mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) is shown in Table 16.

Figure 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 2002. 2003 ESRD CPM Project.



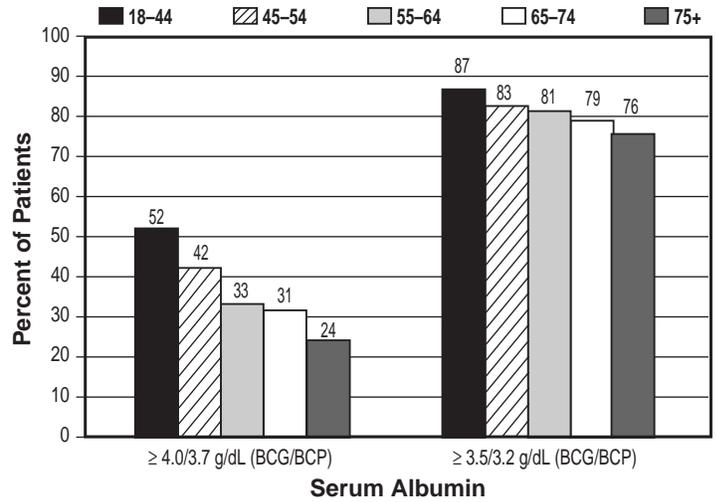
* Note: BCG/BCP = bromocresol green/bromocresol purple laboratory methods.
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.

2. Findings for October–December 2002 compared to previous study periods

No clinically important changes or improvements were noted in the proportion of adult in-center hemodialysis patients with “adequate” or “optimal” serum albumin levels during October–December 2002 compared to previous study periods.

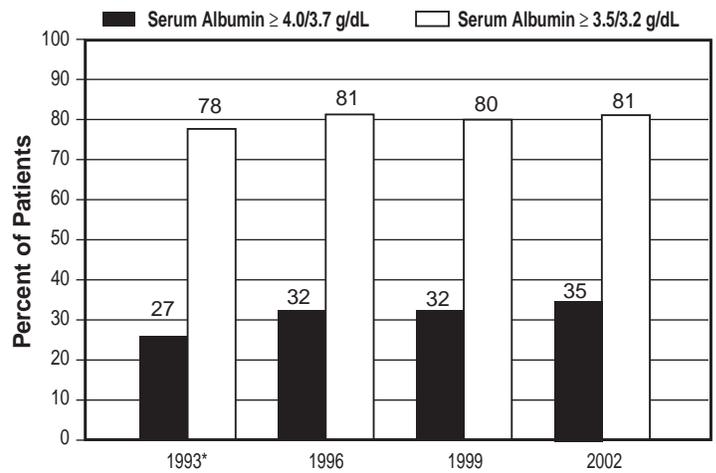
Figure 43 shows the percent of patients with mean serum albumin $\geq 4.0/3.7$ g/dL (40/37 g/L) (BCG/BCP) and the percent of patients with mean serum albumin values $\geq 3.5/3.2$ g/dL (35/32 g/L) (BCG/BCP) during October–December 2002 compared to selected previous study periods.

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 2002. 2003 ESRD CPM Project.



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

Figure 43: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP)** and $\geq 3.5/3.2$ g/dL (BCG/BCP), October–December 2002 compared to selected previous study periods. 2003 ESRD CPM Project.



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

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

TABLE 16: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP method)** by gender, race, ethnicity, age, cause of ESRD, and Network, October-December 2002. 2003 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	31	40	33	34	38	36	36	36	32	45	34	30	39	35	35	25	35	34	35	
GENDER																				
Men	34	46	37	34	42	45	40	43	37	48	40	32	47	44	43	30	44	40	41	
Women	28	31	25	35	32	27	31	28	26	42	28	29	31	25	27	18	25	28	29	
RACE																				
Black	33	48	33	38	41	38	37	41	34	50	44	42	40	38	40	*	35	33	40	
White	30	32	30	32	33	30	33	26	31	39	29	24	37	34	37	24	34	34	32	
ETHNICITY																				
Hispanic	30	51	40	*	*	*	40	*	*	52	*	*	*	38	41	32	38	37	39	
Non-Hispanic	31	38	29	34	37	36	35	36	32	45	35	30	39	34	33	24	35	32	35	
AGE GROUP (years)																				
18-44	42	59	30	49	58	59	47	51	50	56	53	39	51	56	63	36	51	52	52	
45-54	37	49	45	38	39	42	41	47	36	44	41	42	49	41	41	31	41	40	42	
55-64	28	39	35	33	31	22	35	34	28	48	36	38	31	40	25	28	38	33	33	
65-74	28	39	35	33	31	22	35	34	28	48	36	38	31	40	25	28	38	33	31	
75+	28	39	35	33	31	22	35	34	28	48	36	38	31	40	25	28	38	33	24	
CAUSE OF ESRD																				
Diabetes Mellitus	24	29	33	25	31	26	26	30	26	41	23	26	34	30	27	21	30	24	28	
Other Causes	36	46	33	40	42	42	41	41	36	48	42	33	43	42	45	28	40	42	41	
Combined																				

* Value suppressed because $n \leq 10$.

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

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

IV. 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 2002–March 2003 (the serum albumin information is not considered a CPM for this report);
- (2) a description of other quality indicators or data analysis; and
- (3) a comparison of CPM and/or other indicators or findings for October 2002–March 2003 and previous study periods.

A national random sample of adult (≥ 18 years) peritoneal dialysis patients who were alive on December 31, 2002, was selected (sample size=1436). 1354 patients (94%) were included in the sample for analysis.

A. ADEQUACY OF PERITONEAL DIALYSIS

1. CPM Findings for October 2002–March 2003

Data to assess three peritoneal dialysis adequacy CPMs were collected in 2003. The time period from which these data were abstracted was October 2002–March 2003. Tidal peritoneal dialysis patients (n=30) 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: 88% 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.

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: 65% of adult peritoneal dialysis patients who had reported adequacy measurements documented in their chart at least once during the six-month study period had these reported measurements (Kt/V_{urea} and creatinine clearance) calculated in a standard way as described in Peritoneal Dialysis Adequacy CPM II in Appendix 1.

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: 71% of CAPD patients had a mean weekly $Kt/V_{urea} \geq 2.0$ and a mean weekly creatinine clearance ≥ 60 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

ALTERNATE FINDING: 79% (185/233) 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 (33) (a mean weekly $Kt/V_{urea} \geq 2.0$ 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/weekly/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: 66% of cycler patients with a daytime dwell (CCPD patients) had a mean weekly $Kt/V_{urea} \geq 2.1$ and a mean weekly creatinine clearance ≥ 63 L/week/1.73 m² OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

FINDING: 67% of cycler patients without a daytime dwell (NIPD patients) had a mean weekly $Kt/V_{urea} \geq 2.2$ and a mean weekly creatinine clearance ≥ 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.

2. Other Peritoneal Dialysis Adequacy Findings for October 2002-March 2003

There were 491 patients categorized as CAPD patients and 766 patients categorized as cycler patients during the study period. Tidal peritoneal dialysis patients (n=30) 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 1,159 (88%) of the 1,324 patients included for these analyses during the 2003 study period.

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

64% 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 2003 study period (TABLE 18). 58% of cycler patients without a daytime dwell had a mean calculated weekly Kt/V_{urea} and 56% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2003 study period.

42% of patients (n=551) had one or more PET results within 12 months of or during the study period. The distribution of PET results is depicted in Figure 44.

33% of CAPD patients had a total prescription volume of 8000 mL and 31% had a total prescription volume of 10,000 mL (FIGURE 45).

Figure 44: Distribution of Peritoneal Equilibration Test (PET) results for adult peritoneal dialysis patients, October 2002-March 2003. 2003 ESRD CPM Project.

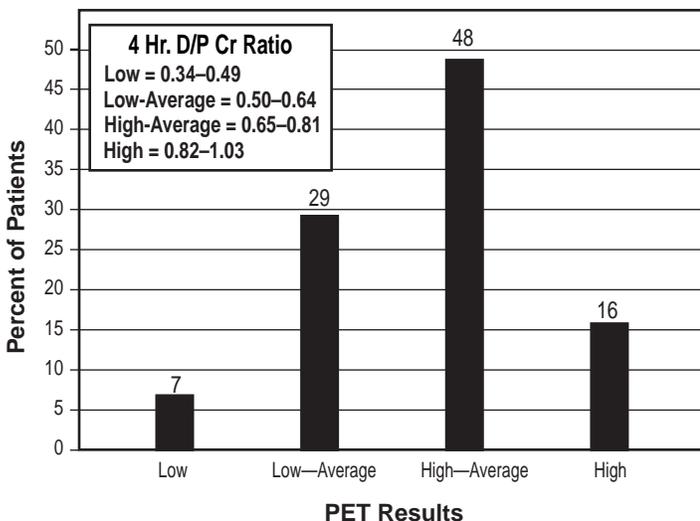
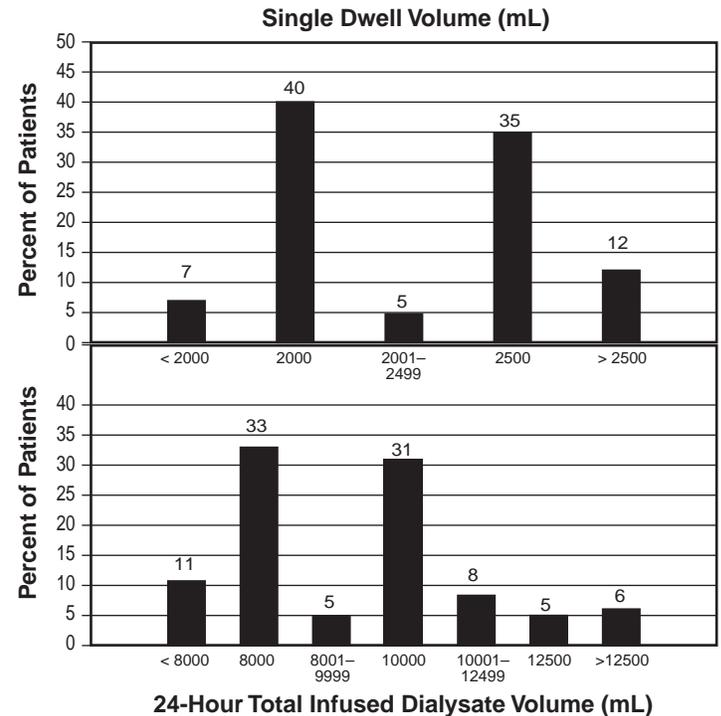


Figure 45: Distribution of single dwell volumes and 24-hour total infused dialysate volumes for adult CAPD patients, October 2002-March 2003. 2003 ESRD CPM Project.



33% of all cycler patients had a single nighttime dwell volume of 2500 mL; 28% had a single nighttime dwell volume of 2000 mL (FIGURE 46). 44% of all cycler patients had a mean of four nighttime exchanges, 25% had a mean of 5 nighttime exchanges, and another 12% had a mean of 3 nighttime exchanges (FIGURE 47).

12% (n = 91) of cycler patients did not have a daytime dwell. 39% of cycler patients with a daytime dwell had a mean single daytime dwell volume of 2000 mL; 22% had a mean single daytime dwell volume of 2500 mL (FIGURE 48). 49% of these patients had one daytime exchange, another 37% had two daytime exchanges (FIGURE 49).

Figure 46: Distribution of mean single nighttime dwell volumes for all adultycler patients, October 2002-March 2003. 2003 ESRD CPM Project.

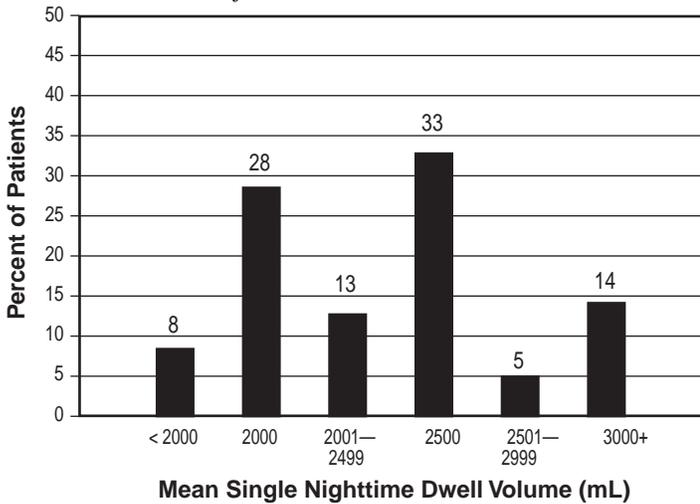


Figure 48: Distribution of mean single daytime dwell volumes for adultycler patients with a daytime dwell, October 2002-March 2003. 2003 ESRD CPM Project.

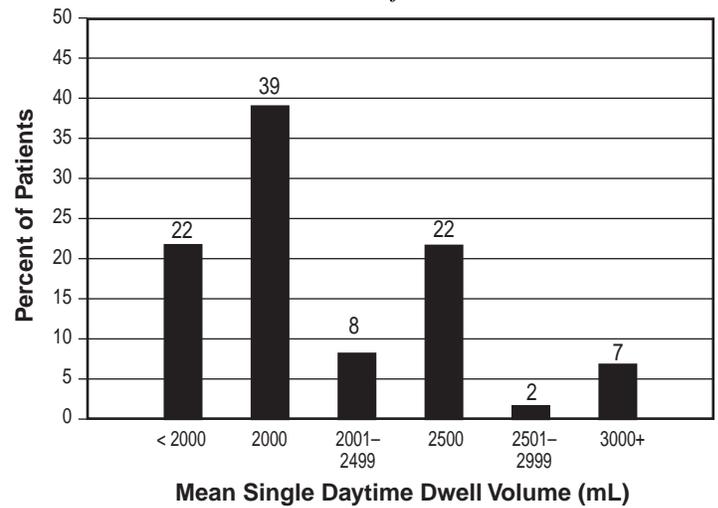


Figure 47: Distribution of the mean number of nighttime exchanges for all adultycler patients, October 2002-March 2003. 2003 ESRD CPM Project.

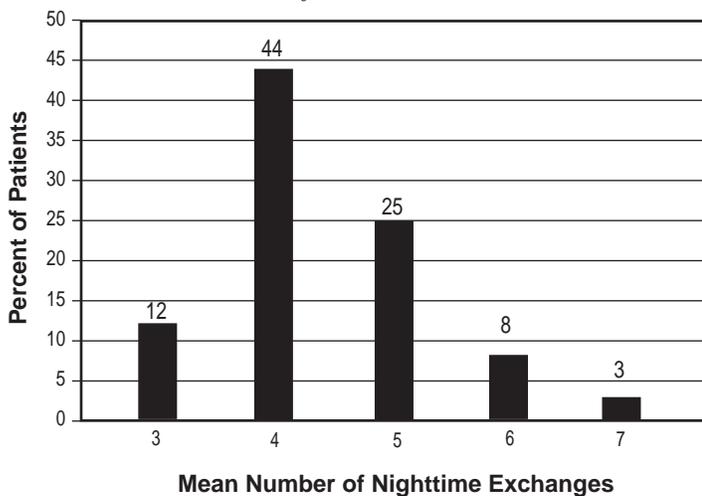
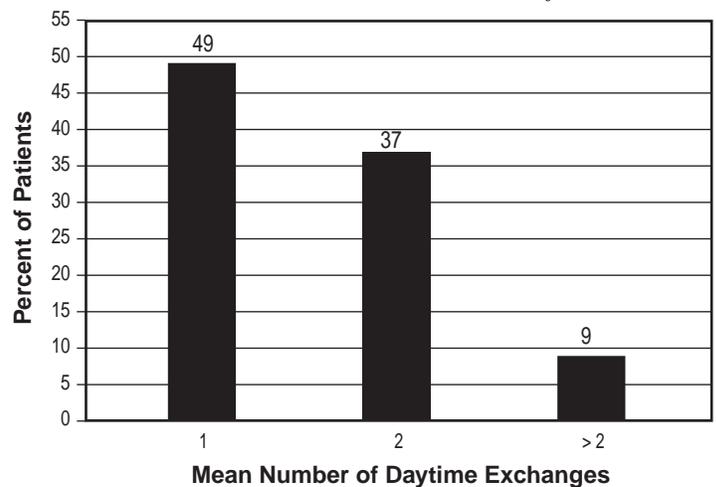


Figure 49: Distribution of the mean number of daytime exchanges for adultycler patients with a daytime dwell, October 2002-March 2003. 2003 ESRD CPM Project.



3. CPM and other Findings for October 2002–March 2003 compared to previous study periods

The adequacy of peritoneal dialysis was reported for 88% of adult peritoneal dialysis patients at least once during the 2003 six-month study period, October 2002–March 2003 (PD Adequacy CPM I), compared to only 82% during the 1999 study period, 83% during the 2000 study period, 85% during the 2001 study period and 86% during the 2002 study period. (FIGURE 4). There has been an increase in the measurement of total solute clearance for urea and creatinine calculated in a standard way reported by facility staff from 1999-2002 (PD Adequacy CPM II) (FIGURE 4).

Although the percent of patients meeting NKF-K/DOQI thresholds for peritoneal dialysis adequacy (3) has increased from the 1999 study period, there was little change in the percent of patients meeting these thresholds from the 2001 study period to the 2003 study period (FIGURE 50).

Figure 50: Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly Kt/V_{urea} and weekly creatinine clearance (PD Adequacy CPM III). 2003 ESRD CPM Project.

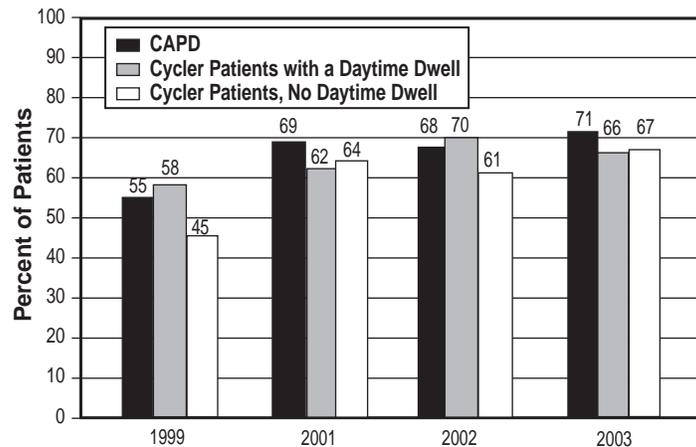


TABLE 17: Percent of adult CAPD patients with mean (\pm SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, by transporter type (4 hr. D/P Cr Ratio), October 2002–March 2003. 2003 ESRD CPM Project.

Adequacy Measure	Oct 2000-Mar 2001		Oct 2001-Mar 2002		Oct 2002-Mar 2003	
	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%
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)
median	2.26	2.32	2.27	2.23	2.26	2.40
Weekly Creatinine Clearance (L/week/1.73 m²)						
% meeting NKF-K/DOQI	76%	79%	73%	80%	66%	79%
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)
median	78.6	68.5	72.5	67.6	72.8	69.6

[^] For CAPD patients, the delivered PD dose should be a weekly $Kt/V_{urea} \geq 2.0$ and a weekly creatinine clearance ≥ 60 L/week/1.73m² for high-average and high transporters, and ≥ 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 = 0.82-1.02

TABLE 18: Percent of adult cycler patients with mean (\pm SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, October 2002–March 2003. 2003 ESRD CPM Project.

Adequacy Measure	Oct 2000-Mar 2001		Oct 2001-Mar 2002		Oct 2002-Mar 2003	
	with daytime dwell	no daytime dwell	with daytime dwell	no daytime dwell	with daytime dwell	no daytime dwell
Weekly Kt/V_{urea}						
% meeting NKF-K/DOQI [^]	64%	53%	66%	61%	64%	58%
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)
median	2.24	2.22	2.25	2.29	2.25	2.38
Weekly Creatinine Clearance						
% meeting NKF-K/DOQI	55%	61%	55%	53%	49%	56%
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)
median	65.7	75.3	65.7	68.1	62.3	70.2

[^] For cycler patients with daytime dwell (CCPD patients): $Kt/V_{urea} \geq 2.1$; creatinine clearance ≥ 63 L/week/1.73m²

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

B. ANEMIA MANAGEMENT

1. CPM Findings for October 2002–March 2003

Data to assess three anemia management CPMs were collected in 2003. The time period from which these data were abstracted was October 2002–March 2003.

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

FINDING: For the six-month study period, 39% of the peritoneal dialysis patients who met the inclusion criteria (n=1227) 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 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=1219) had at least two documented (measured) transferrin saturation values and at least two documented (measured) serum ferritin concentration values during October 2002–March 2003.

Anemia Management CPM IIb — For all anemic patients (hemoglobin < 11 g/dL [110 g/L]) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation ≥ 20% were documented during the six-month study period.

FINDING: 81% of the adult peritoneal dialysis patients who met the inclusion criteria (n=1219) had at least one documented transferrin saturation ≥ 20% and at least one documented serum ferritin concentration ≥ 100 ng/mL during October 2002–March 2003.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 g/dL [110 g/L]) or patients prescribed Epoetin, with at least one transferrin saturation < 20% or at least one serum ferritin concentration < 100 ng/mL during the study period are prescribed intravenous iron; UNLESS the mean transferrin saturation was ≥ 50% or the mean serum ferritin concentration was ≥ 800 ng/ml; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

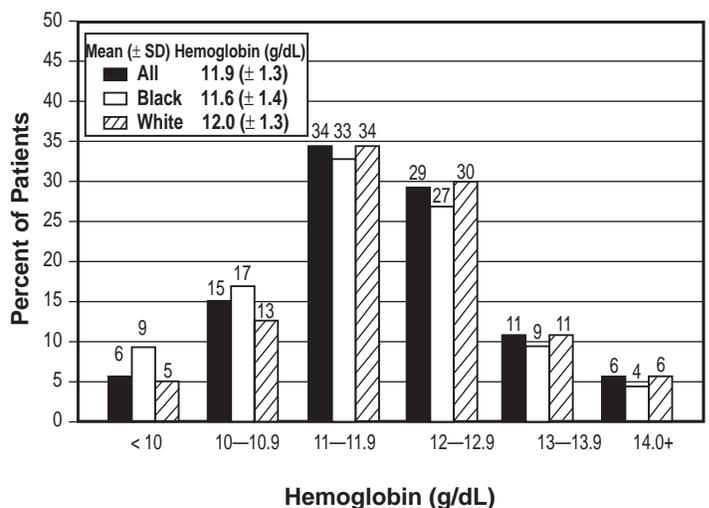
FINDING: 32% of the peritoneal dialysis patients who met the inclusion criteria (n=524) were prescribed intravenous iron at least once during the six-month study period during October 2002–March 2003.

2. Other Anemia Management Findings for October 2002–March 2003

The mean (± SD) hemoglobin for adult peritoneal dialysis patients in the sample was 11.9 (± 1.3) g/dL (119 [± 13] g/L). The distribution of mean hemoglobin values for Black and White patients is depicted in Figure 51. The mean hemoglobin values and the proportion of patients within different hemoglobin categories for gender, race, ethnicity, age, diagnosis, duration of dialysis, mean serum albumin level and weekly creatinine clearance are shown in Table 19. 79% of patients had a mean hemoglobin ≥ 11 g/dL (110 g/L) (FIGURE 7). Significantly more Whites and patients older than 55 years had a mean hemoglobin ≥ 11 g/dL (110 g/L) compared to Blacks, and younger patients (TABLE 19). A larger percentage of patients with higher mean serum albumin and weekly creatinine clearance had a mean hemoglobin ≥ 11 g/dL (110 g/L) compared to patients with lower mean serum albumin and weekly creatinine clearance values. Nationally, 66% of patients prescribed Epoetin had a mean hemoglobin 11–12.9 g/dL (110–129 g/L).

The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was 6% (FIGURE 51, TABLE 19). The prevalence of patients with mean hemoglobin < 10 g/dL (100 g/L) was significantly higher in Blacks compared to Whites, for patients 18–54 years old compared to older patients, patients dialyzing two or more years compared to patients dialyzing less than two years, and in patients with lower mean serum albumin and creatinine clearance values compared to patients with higher mean serum albumin and creatinine clearance values (TABLE 19).

Figure 51: Distribution of mean hemoglobin values for adult peritoneal dialysis patients in the US, by race, October 2002–March 2003. 2003 ESRD CPM Project.



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

TABLE 19: Mean hemoglobin values (g/dL) for adult peritoneal dialysis patients, by patient characteristics, October 2002-March 2003. 2003 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	11.9	6	15	34	29	11	6
GENDER							
Men	12.0	6	13	34	27	12	8
Women	11.8	7	16	34	31	9	3
RACE							
American Indian/ Alaska Native	11.8	*	*	*	*	*	*
Asian/Pacific Islander	12.1	*	16	33	27	*	*
Black	11.6	9	17	33	27	9	4
White	12.0	5	13	34	30	11	6
Other/Unknown	12.0	*	*	41	32	*	*
ETHNICITY							
Hispanic	11.9	7	11	35	30	11	*
Non-Hispanic	11.9	6	15	34	29	11	6
AGE GROUP (years)							
18-44	11.8	9	14	35	28	8	6
45-54	11.7	9	18	32	28	9	5
55-64	12.1	5	13	35	26	12	8
65-74	12.0	*	13	34	32	14	5
75+	12.0	*	14	29	40	12	*
CAUSE of ESRD							
Diabetes Mellitus	11.9	6	15	35	28	12	4
Hypertension	11.9	5	17	30	35	9	4
Glomerulonephritis	11.8	8	14	37	28	8	5
Other/Unknown	12.0	8	12	33	27	12	9
DURATION of DIALYSIS (years)							
< 0.5	12.0	*	14	29	32	13	6
0.5-0.9	12.1	*	12	34	25	17	7
1.0-1.9	11.9	4	15	34	33	9	4
2.0-2.9	11.9	9	12	36	28	8	7
3.0-3.9	11.7	9	16	33	27	11	*
4.0+	11.8	7	18	35	27	8	5
MEAN SERUM ALBUMIN (g/dL)							
≥ 3.5/3.2 (BCG/BCP) [^]	12.1	4	12	31	33	13	7
< 3.5/3.2 (BCG/BCP)	11.6	10	19	37	24	8	3
MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m²)							
≥60	12.0	4	14	34	31	11	6
<60	11.7	8	17	36	27	9	4

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

The mean (± SD) transferrin saturation for the patients in this sample was 30.3 (± 12.2)% and 83% of patients had mean transferrin saturation ≥ 20%. The mean (± SD) serum ferritin concentration was 425 (± 399) ng/mL, with 84% of patients having a mean serum ferritin concentration ≥ 100 ng/mL. 62 patients (5% of patients) had both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

89% of the patients in the sample for analysis were prescribed Epoetin during the six-month study period. Epoetin was prescribed 99% 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), 97% 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), 70% of the time when mean hemoglobin values were between 13-13.9 g/dL (130-139 g/L) and 49% 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, 99% were prescribed Epoetin by the SC route; 4% were prescribed Epoetin by the IV route (groups not mutually exclusive). The mean (± SD) weekly Epoetin dose for patients prescribed Epoetin by the SC route was 163.0 (± 140.9) units/kg/week; by the IV route was 208.5 (± 188.2) units/kg/week.

Iron use was assessed during this study period. Iron by either the oral or IV route was prescribed at least once during the six months for 61% of the patients in this sample, and three times over the six-month period for 38% of the patients. Of the patients prescribed iron, 77% were prescribed oral iron and 36% 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=62), 74% were prescribed either oral or IV iron at least once during the six months, and 47% three times over the six-month study period. 27% of these patients were prescribed IV iron at least once during the six-month study period.

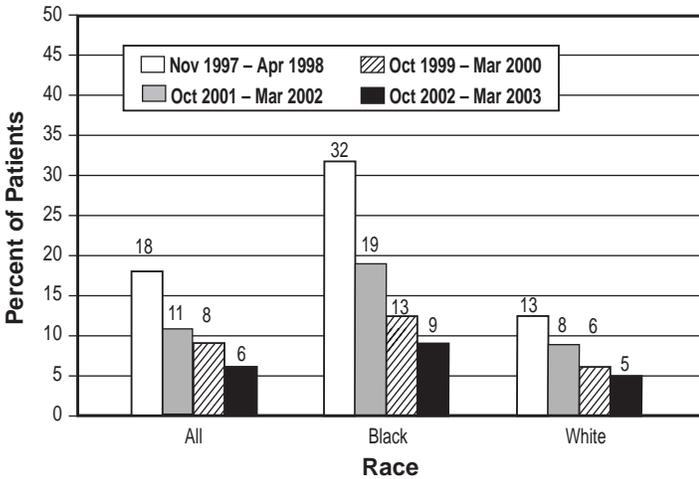
3. CPM and other Findings for October 2002– March 2003 compared to previous study periods

The percent of peritoneal dialysis patients with mean hemoglobin ≥ 11 g/dL (110 g/L) increased from 55% to 79% from the 1998 to the 2003 study periods (FIGURE 7). This improvement was noted for both Black patients (from 38% to 73%) and for White patients (63% to 81%). The mean (± SD) hemoglobin increased from 11.8 (± 1.4) g/dL (118 [± 14] g/L) during the 2002 study period to 11.9 (± 1.3) g/dL (119 [± 13] g/L) during the 2003 study period (FIGURE 8). The distribution of mean hemoglobin values over these four study periods was not significantly different by modality (CAPD vs. cycler).

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 6% in the 2003 study period (FIGURE 52).

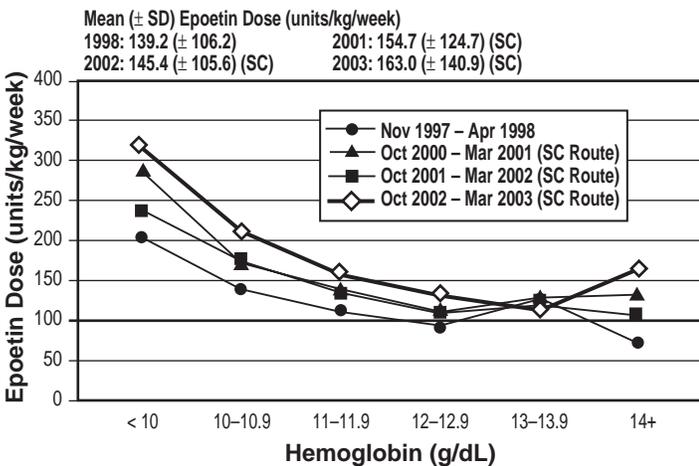
Figure 53 depicts the trend in Epoetin dosing from the 1998 study period to the 2003 study period, with an increasing mean weekly Epoetin dose (units/kg/week) for patients prescribed Epoetin in lower hemoglobin categories. IV doses were generally larger than SC doses (data not displayed due to small cell sizes).

Figure 52: Percent of adult peritoneal dialysis patients with mean hemoglobin < 10 g/dL, by race, October 2002–March 2003 compared to previous study periods. 2003 ESRD CPM Project.



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

Figure 53: Mean weekly Epoetin dose (units/kg/week) by hemoglobin category for adult peritoneal dialysis patients prescribed Epoetin, October 2002–March 2003 compared to previous study periods. 2003 ESRD CPM Project.

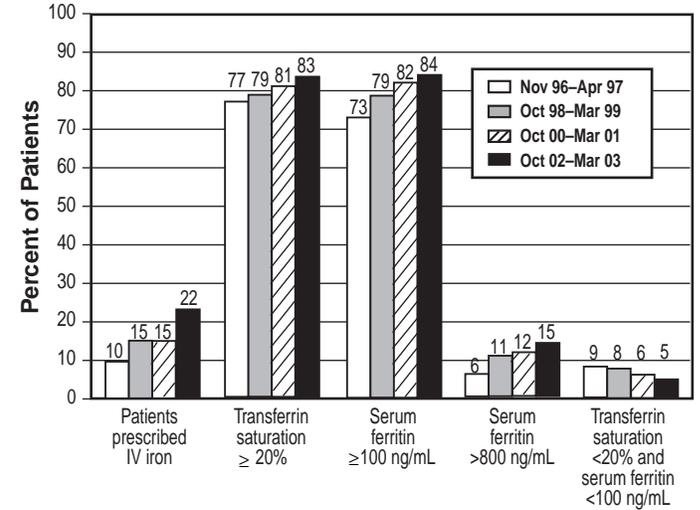


Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

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 2002–March 2003 study periods.

Figure 54 depicts the status of iron stores for the sampled patients for study period 2003 compared to selected previous study periods. Overall, 22% of patients were prescribed IV iron during the 2003 study period compared to 10% during the 1997 study period. 5% of patients had a mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL during the 2003 study period compared to 9% during the 1997 study period.

Figure 54: Percent of adult peritoneal dialysis patients with specific anemia management indicators, October 2002–March 2003 compared to selected previous study periods. 2003 ESRD CPM Project



C. SERUM ALBUMIN

1. Findings for October 2002–March 2003

The mean (± SD) serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method (n=1,232) was 3.6 (± 0.5) g/dL (36 [± 5] g/L) and by the BCP method (n=117) was 3.2 (± 0.5) g/dL (32 [± 5] g/L). “Adequate” serum albumin was defined for this report as ≥ 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP). “Optimal” serum albumin was defined as ≥ 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP). Nationally, 18% of patients had a mean serum albumin ≥ 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP). 60% of patients had a mean serum albumin ≥ 3.5/3.2 g/dL (35/32 g/L) by the BCG/BCP method (TABLE 20).

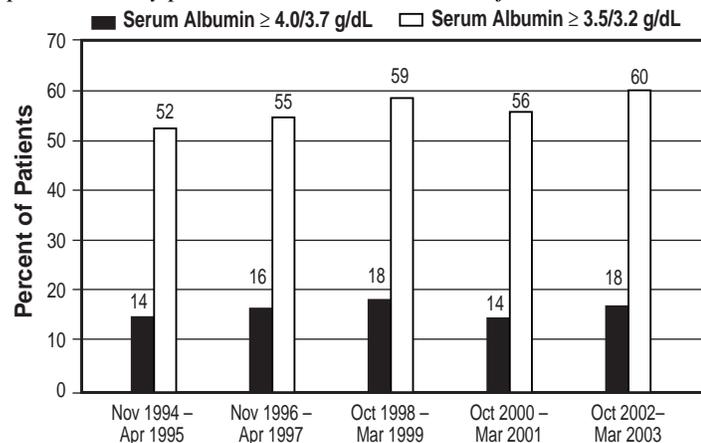
The percent of patients with mean serum albumin defined as either “adequate” or “optimal” by gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters is shown in Table 20. The percent of patients with “optimal” mean serum albumin tended to be higher for men compared 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 (110 g/L) compared to patients with lower mean hemoglobin values. (TABLE 20).

2. Findings for October 2002–March 2003 compared to previous study periods

Figure 55 shows the percent of patients with mean serum albumin ≥ 4.0/3.7 g/dL (40/37 g/L) (BCG/BCP) and the percent of patients with mean serum albumin ≥ 3.5/3.2 g/dL (35/32 g/L) (BCG/BCP) during the 2003 study period compared to previous study periods.

Although not consistent, there has been slight improvement in the proportion of adult peritoneal dialysis patients achieving either “adequate” or “optimal” mean serum albumin levels from the 1995 study period to the 2003 study period.

Figure 55: Percent of adult peritoneal dialysis patients with mean serum albumin ≥ 4.0/3.7 g/dL (BCG/BCP)* and ≥ 3.5/3.2 g/dL (BCG/BCP), October 2002–March 2003 compared to previous study periods. 2003 ESRD CPM Project.



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

TABLE 20: Percent of adult peritoneal dialysis 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 US, by patient characteristics, October 2002–March 2003. 2003 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin	
	≥ 4.0/3.7 g/dL	≥ 3.5/3.2 g/dL
TOTAL	18	60
GENDER		
Men	21	62
Women	15	57
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	29	68
Black	17	55
White	17	60
Other/Unknown	27	73
ETHNICITY		
Hispanic	19	66
Non-Hispanic	18	59
AGE GROUP (years)		
18-44	30	69
45-54	21	59
55-64	13	58
65-74	10	54
75+	*	50
CAUSE of ESRD		
Diabetes mellitus	10	47
Hypertension	20	68
Glomerulonephritis	27	69
Other/Unknown	23	63
DURATION of DIALYSIS (years)		
< 0.5	12	51
0.5-0.9	21	60
1.0-1.9	20	65
2.0-2.9	20	60
3.0-3.9	17	62
4.0+	17	59
MEAN Hgb (g/dL)		
≥ 11	21	64
< 11	7	45
MEAN WEEKLY CREATININE CLEARANCE (L/week/1.73m²)		
≥ 60	17	61
< 60	22	61

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

V. PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS

All patients aged < 18 years identified as receiving in-center hemodialysis on December 31, 2002 were included in this study (n=787). 663 patients (84%) of this group met the case definition and were included in the sample for analysis. (See footnote to Table 5 on page 18 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 2002;
- (2) a comparison of core indicator results or findings for October-December 2002 and previous study periods for patients 12 to < 18 years only.

A. CLEARANCE

1. Findings for October–December 2002 (for patients <18 years)

The percent of patients in the sample for analysis with at least one calculated spKt/V measure available (n=628) who had a mean spKt/V ≥ 1.2 in the last quarter of 2002 was 90%. 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 2002 was 1.57 (± 0.31) (FIGURE 56). The distribution of spKt/V values for these patients is shown in Figure 56. The spKt/V was calculated using the Daugirdas II method; one blood sample was obtained post-dialysis reflecting a single pool distribution (6). The mean (± SD) delivered calculated URR for this population was 72.9% (± 7.5%). 88% of patients had a mean delivered calculated URR ≥ 65%.

Figure 56: 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 2002. 2003 ESRD CPM Project.

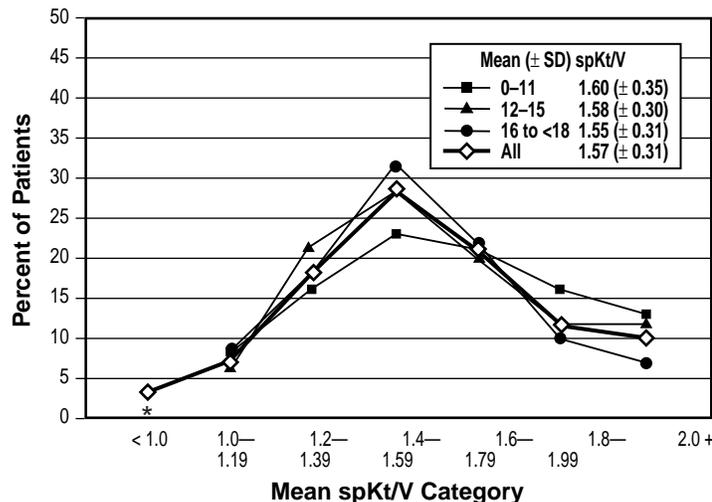


TABLE 21: Mean delivered calculated, single session spKt/V for all pediatric (aged < 18 years) in-center hemodialysis patients and percent of patients with mean spKt/V ≥ 1.2, by patient characteristics, October-December 2002. 2003 ESRD CPM Project.

Patient Characteristics	Mean spKt/V	% spKt/V ≥ 1.2
TOTAL	1.57	90
GENDER		
Males	1.53	88
Females	1.63	92
RACE		
American Indian/ Alaska Native	1.46	*
Asian/Pacific Islander	1.61	84
Black	1.55	89
White	1.59	91
Other/Unknown	1.57	92
ETHNICITY		
Hispanic	1.62	97
Non-Hispanic	1.56	88
AGE GROUP (years)		
0-4	1.62	95
5-9	1.69	94
10-14	1.56	90
15 to <18	1.55	89
DIALYSIS SESSION LENGTH (minutes)		
<180	1.44	82
180-209	1.51	88
210-239	1.62	90
240+	1.68	95
DURATION of DIALYSIS (years)		
< 0.5	1.43	76
0.5-0.9	1.53	90
1.0-1.9	1.58	92
2.0-2.9	1.60	93
3.0-3.9	1.58	98
4.0+	1.68	94
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)		
8.3-27.2	1.65	94
27.3-38.6	1.61	91
38.7-48.3	1.65	94
48.4-60.0	1.55	89
60.1-170.2	1.41	82
ACCESS TYPE		
AV Fistula	1.58	92
AV Graft	1.71	99
Catheter	1.53	87
MEAN Hgb (g/dL)		
≥ 11	1.58	91
< 11	1.57	88
MEAN SERUM ALBUMIN (g/dL)		
≥ 3.5/3.2 (BCG/BCP) [^]	1.59	91
< 3.5/3.2 (BCG/BCP)	1.51	82

*Value suppressed because n ≤ 10.

[^]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, duration of dialysis, quintile of post-dialysis body weight, access type, and mean hemoglobin and serum albumin categories, are shown in Table 21.

The mean (\pm SD) time spent on dialysis per dialysis session was 204 (\pm 30) minutes. The mean time spent on dialysis was longer for males compared to females (206 minutes vs. 201 minutes), Blacks compared to Whites (208 minutes vs. 202 minutes), for patients aged 16 to < 18 years compared to patients aged 12 to 15 years and 0 to 11 years (209 minutes vs. 205 and 195 minutes respectively), for patients dialyzing six months or longer compared to patients dialyzing less than six months (206 minutes vs. 197 minutes), for patients in the highest quintile of post-dialysis body weight compared to those patients in the lowest quintile (217 minutes vs. 193 minutes) and for patients dialyzed with an AVF compared to those patients with an AV graft or catheter access (212 minutes vs. 209 minutes and 200 minutes, respectively).

2. Findings for October-December 2002 compared to previous study periods (for patients 12 to <18 years)

The mean (\pm SD) delivered spKt/V among patients aged 12 to < 18 years increased from 1.47 (\pm 0.38) in October-December 1999 to 1.56 (\pm 0.30) in October-December 2002 (FIGURE 9). The percent of these patients receiving dialysis with a mean delivered spKt/V ≥ 1.2 increased from 79% in late 1999 to 90% in late 2002. This improvement occurred for both males and females and for White and Black patients (FIGURES 57, 58).

There was very little change in dialysis session length from late 1999 to late 2002.

Figure 57: Percent of all pediatric (aged ≥ 12 to < 18 years) male in-center hemodialysis patients with mean delivered calculated, single session spKt/V ≥ 1.2 , by race, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.

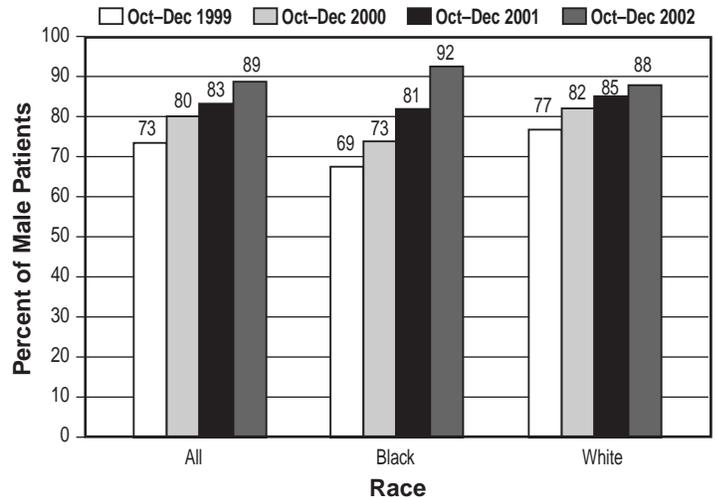
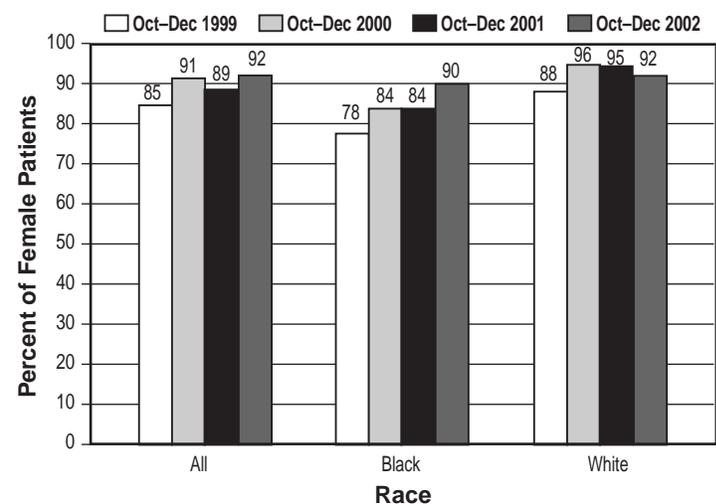


Figure 58: Percent of all pediatric (aged ≥ 12 to < 18 years) female in-center hemodialysis patients with mean delivered calculated, single session spKt/V ≥ 1.2 , by race, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



B. VASCULAR ACCESS

1. Findings for October-December 2002 (for patients <18 years)

28% of patients were dialyzed with an AV fistula (AVF), 15% with an AV graft, and 57% with a catheter during October-December 2002 (TABLE 22). The percent of patients with an AVF, AV graft and catheter by selected patient characteristics is shown in Table 22.

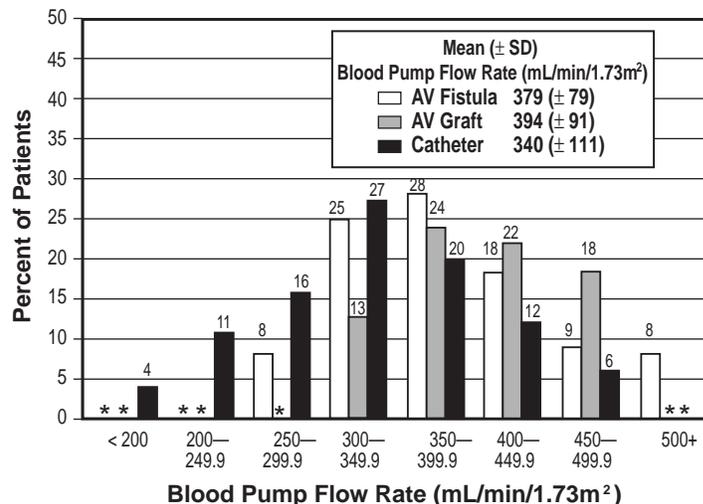
TABLE 22: Vascular access type for all pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2002, by selected patient characteristics. 2003 ESRD CPM Project.

Patient Characteristics	Percent of Patients with		
	AV Fistula	AV Graft	Catheter
TOTAL	28	15	57
GENDER			
Males	33	14	53
Females	21	16	62
RACE			
American Indian/ Alaska Native	*	*	*
Asian/Pacific Islander	*	*	52
Black	28	15	57
White	28	16	56
Other/Unknown	23	17	61
ETHNICITY			
Hispanic	27	17	56
Non-Hispanic	28	15	57
AGE GROUP (years)			
0-4	*	*	96
5-9	*	*	82
10-14	21	16	63
15 to <18	41	16	43
DURATION of DIALYSIS (years)			
< 0.5	*	*	88
0.5-0.9	33	9	59
1.0-1.9	28	17	55
2.0-2.9	34	23	43
3.0-3.9	39	*	50
4.0+	33	25	42

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

The mean (± SD) delivered blood pump flow rate normalized for BSA 60 minutes into the dialysis session was 379 (± 79) mL/min/1.73m² for patients dialyzed with an AVF, 394 (± 91) mL/min/1.73m² for patients dialyzed with an AV graft, and 340 (± 111) mL/min/1.73m² for patients with a catheter access during October-December 2002 (FIGURE 59).

Figure 59: 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 2002. 2003 ESRD CPM Project.



* Values suppressed because n ≤ 10.

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

375 (57%) patients had a catheter as their current access in late 2002. In patients who had catheters for hemodialysis access, no AVF or AV graft was planned for 47% of the patients, another 26% had no AVF or AV graft created at the end of 2002, and an AVF or AV graft had been created but was not ready to cannulate for 13% (TABLE 23). 3% of patients were not candidates for AVF or AV graft placement as all sites had been exhausted.

Table 23: Reasons for catheter placement in all pediatric (aged < 18 years) in-center hemodialysis patients using catheters on their last hemodialysis session during October-December 2002. 2003 ESRD CPM Project.

Reason	n (%)
TOTAL	375 (100)
No fistula or graft surgically planned	177 (47)
Patient size too small for AV fistula/graft	73
Patient preference	55
Renal transplantation scheduled	35
Physician preference	35
Peripheral vascular disease	*
No fistula or graft surgically created at this time	96 (26)
Fistula or graft maturing, not ready to cannulate	48 (13)
Temporary interruption of fistula or graft due to clotting or revisions	16 (4)
All fistula or graft sites in this patient's body have been exhausted	12 (3)
Other	26 (7)

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

47% of patients (n=311) were dialyzed with a chronic catheter, defined as the continuous use of a catheter 90 days or longer, during October-December 2002.

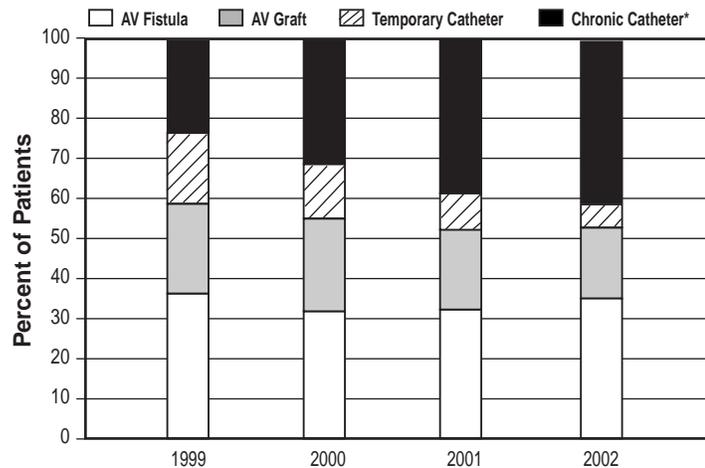
47% of patients (134/284) with an AVF or an AV graft had their access routinely monitored for stenosis. (See Appendix 1 for a complete description of the types of stenosis monitoring). Within this subset of patients, 54% were monitored with dynamic venous pressure, 19% with static venous pressure, 17% with the dilution technique, and 20% had other types of monitoring (groups not mutually exclusive).

2. Findings for October-December 2002 compared to previous study periods (for patients 12 to < 18 years)

A lower percent of patients was dialyzed with an AVF in late 2002 compared to late 1999 (35% vs. 37%, respectively) (FIGURES 10, 60). A higher percent of patients was dialyzed with a catheter in late 2002 compared to late 1999 (48% vs. 41%, respectively).

23% of patients were dialyzed with a chronic catheter continuously for 90 days or longer during October-December 1999 and 41% during October-December 2002 (FIGURE 10, 60).

Figure 60: 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 2002 compared to previous study periods. 2003 ESRD CPM Project.



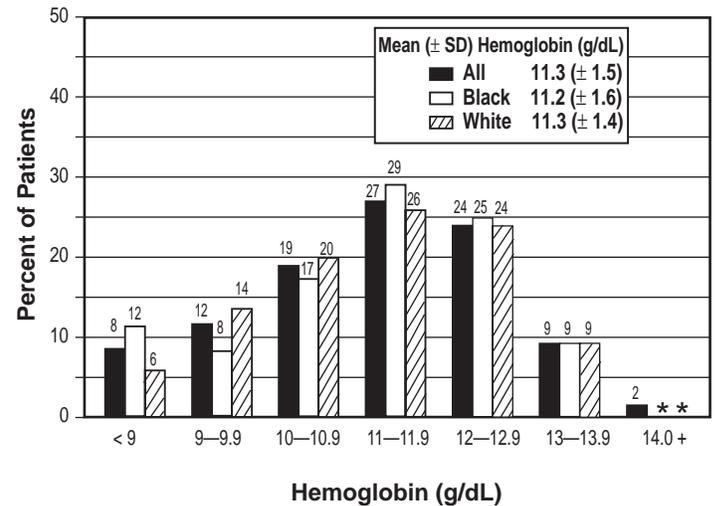
*Chronic catheter use defined as continuous catheter use 90 days or longer.

C. ANEMIA MANAGEMENT

1. Findings for October-December 2002 (for patients <18 years)

The distribution of mean hemoglobin values for all patients, and by race, is shown in Figure 61. The mean hemoglobin values and distribution of hemoglobin values by gender, race, ethnicity, age, diagnosis, duration of dialysis, access type, and mean spKt/V and serum albumin levels are shown in Table 24.

Figure 61: Distribution of mean hemoglobin values (g/dL) for all pediatric (aged < 18 years) in-center hemodialysis patients, by race, October-December 2002. 2003 ESRD CPM Project.



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

The percent of patients with mean hemoglobin < 9 g/dL (90 g/L) was 8%. The percent of patients with mean hemoglobin < 10 g/dL (100 g/L) was 20%. 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 (36% vs. 17%, respectively), and higher in patients with a catheter access compared to patients dialyzed with an AVF (25% vs. 8%). 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) (43% vs. 15%).

TABLE 24: Mean hemoglobin values (g/dL) and distribution of hemoglobin values for all pediatric (aged < 18 years) in-center hemodialysis patients, by patient characteristics, October-December 2002. 2003 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	11.3	8	12	19	27	24	9	*
GENDER								
Males	11.3	8	11	20	26	25	10	*
Females	11.2	8	13	17	28	23	8	*
RACE								
American Indian/ Alaska Native	11.7	*	*	*	*	*	*	*
Asian/Pacific Islander	11.3	*	*	*	*	*	*	*
Black	11.2	12	8	17	29	25	9	*
White	11.3	6	14	20	26	24	9	*
Other/Unknown	11.5	*	*	20	29	24	*	*
ETHNICITY								
Hispanic	11.4	6	10	17	27	28	10	*
Non-Hispanic	11.2	8	12	19	27	24	9	*
AGE GROUP (years)								
0-4	10.2	*	*	*	*	*	*	*
5-9	11.1	*	*	26	27	19	*	*
10-14	11.2	8	14	15	28	24	10	*
15 to < 18	11.4	6	7	20	28	28	9	*
DURATION OF DIALYSIS (years)								
< 0.5	10.7	16	20	19	20	17	*	*
0.5-0.9	11.6	*	11	16	25	25	18	*
1.0-1.9	11.4	*	10	19	30	24	*	*
2.0-2.9	11.6	*	*	*	31	29	*	*
3.0-3.9	11.1	*	*	*	*	34	*	*
4.0+	11.1	9	11	21	27	26	*	*
ACCESS TYPE								
AV Fistula	11.6	*	*	17	32	31	10	*
AV Graft	11.3	*	14	*	29	31	*	*
Catheter	11.1	10	15	21	24	19	9	*
MEAN spKt/V								
≥ 1.2	11.3	7	11	19	27	25	9	*
< 1.2	11.1	*	*	19	27	*	*	*
MEAN SERUM ALBUMIN (g/dL)								
≥ 3.5/3.2 (BCG/BCP) [^]	11.5	6	9	17	29	26	11	*
< 3.5/3.2 (BCG/BCP)	10.2	18	25	25	17	13	*	*

* Value suppressed because n ≤ 10.

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

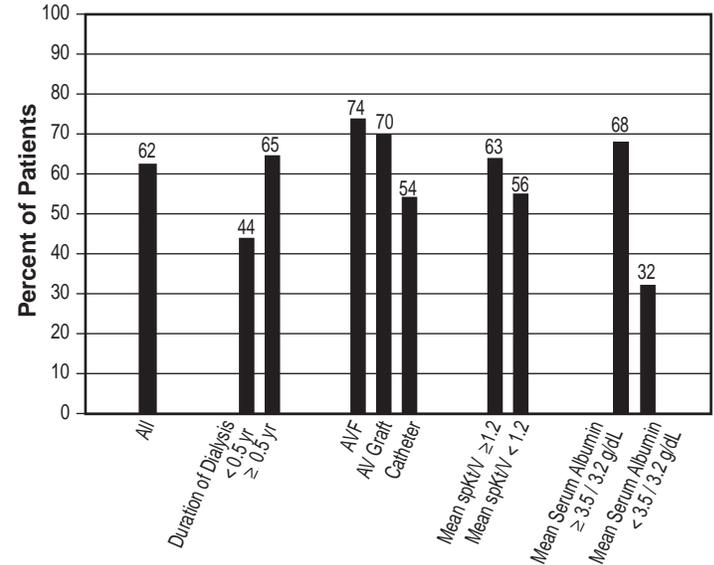
Note: Percentages may not add up to 100% due to rounding.

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.

62% 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 62.

Figure 62: 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 2002. 2003 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.

97% of patients were prescribed Epoetin during the study period. Of the patients prescribed Epoetin, 93% were prescribed Epoetin by the IV route; and 9% by the SC route (groups not mutually exclusive). The mean (± SD) weekly Epoetin dose for patients prescribed Epoetin by the IV route was 358.1 (± 316.6) units/kg/week; by the SC route, 242.1 (± 196.5) units/kg/week.

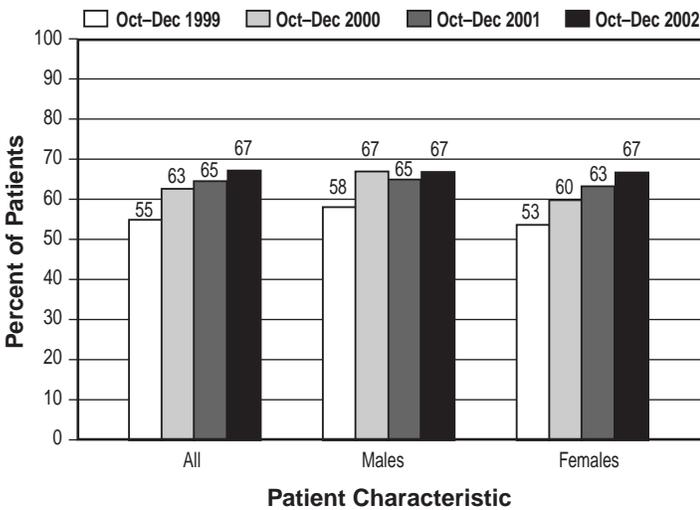
The mean (± SD) transferrin saturation for these patients was 30.1 (± 15.4) %. 75% of patients had a mean transferrin saturation ≥ 20%. The mean (± SD) serum ferritin concentration was 418.9 (± 382.7) ng/mL. 80% of patients had a mean serum ferritin concentration ≥ 100 ng/mL. 14% (n=89) of patients had a mean serum ferritin concentration > 800 ng/mL during the study period.

78% of patients were prescribed either IV or oral iron at least once during the three-month study period. The percent of patients with IV iron prescribed was 65%. The mean administered IV iron dose was 242.2 (± 187.7) mg/month. The mean administered IV iron dose per kg per month was 6.23 (± 5.18) mg/kg/month. For the subset of patients with both mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL (n=51 or 8% of patients), only 53% were prescribed IV iron at least once during the three-month study period.

2. Findings for October-December 2002 compared to previous study periods (for patients 12 to <18 years)

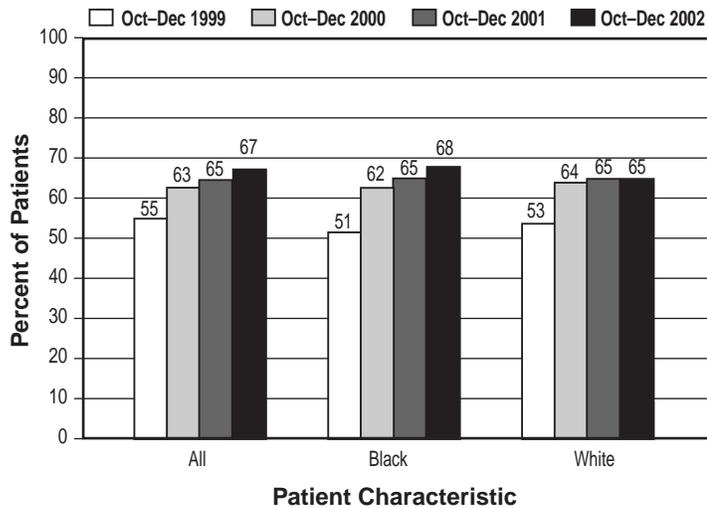
The mean (\pm SD) hemoglobin from late 1999 to late 2002 among patients 12 to < 18 years increased from 11.0 (\pm 1.6) g/dL (110 [\pm 16] g/L) to 11.4 (\pm 1.4) g/dL (114 [\pm 14] g/L) (FIGURE 11). The percent of these patients with a mean hemoglobin \geq 11 gm/dL (110 g/L) increased from 55% to 67% (FIGURES 63, 64). This improvement occurred for both male and female patients and for Whites and Blacks (FIGURES 63, 64).

Figure 63: Percent of pediatric (aged \geq 12 to < 18 years) in-center hemodialysis patients with mean hemoglobin \geq 11 g/dL, by gender, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

Figure 64: Percent of pediatric (aged \geq 12 to < 18 years) in-center hemodialysis patients with mean hemoglobin \geq 11 g/dL, by race, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.

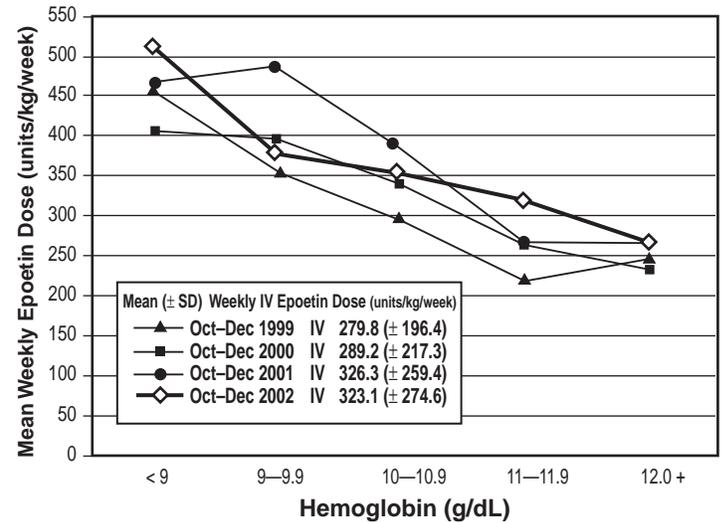


Note: To convert hemoglobin conventional units of g/dL to SI units (g/L), multiply by 10.

In addition to the improvement in the percent of patients with mean hemoglobin \geq 11 g/dL (110 g/L), there was also a decrease in the percent of patients with mean hemoglobin < 10 g/dL (100 g/L). In October-December 1999, 26% of Black patients and 21% of White patients had a mean hemoglobin < 10 g/dL (100 g/L), while in October-December 2002, 16% of Black patients and 15% of White patients had a mean hemoglobin < 10 g/dL (100 g/L).

Figure 65 depicts the trend for increasing prescribed weekly Epoetin dosing (units/kg/week) from late 1999 to late 2002. Prescribed weekly SC Epoetin doses were lower than the prescribed weekly IV Epoetin doses at most hemoglobin categories examined.

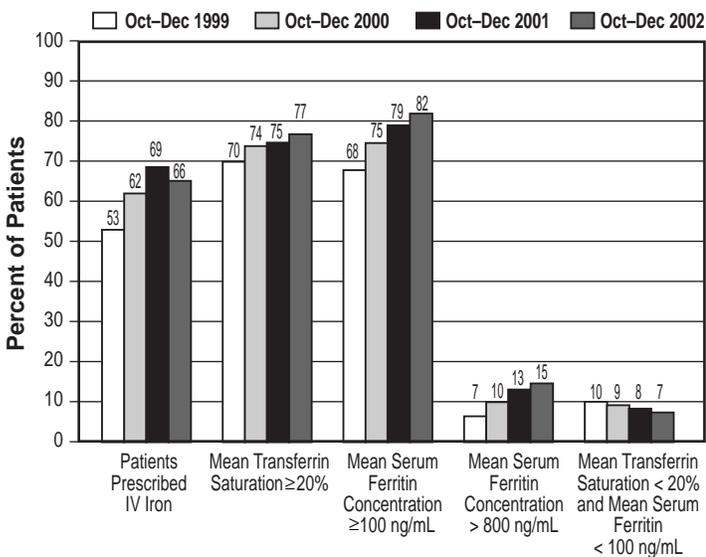
Figure 65: Mean prescribed weekly IV Epoetin dose (units/kg/week) for pediatric (aged \geq 12 to < 18 years) in-center hemodialysis patients, by hemoglobin category, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



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

Iron management for pediatric patients aged 12 to < 18 years improved over the four study periods (FIGURE 66).

Figure 66: Iron management parameters for pediatric (aged ≥ 12 to < 18 years) in-center hemodialysis patients, October-December 2002 compared to previous study periods. 2003 ESRD CPM Project.



D. SERUM ALBUMIN

1. Findings for October-December 2002 (for patients < 18 years)

The mean (\pm SD) serum albumin value for pediatric patients whose value was determined by the BCG method ($n=568$) was $3.9 (\pm 0.5)$ g/dL ($39 [\pm 5]$ g/L), and by the BCP method ($n=94$) was $3.7 (\pm 0.5)$ g/dL ($37 [\pm 5]$ g/L). "Adequate" serum albumin was defined for this report as $\geq 3.5/3.2$ g/dL ($35/32$ g/L) (BCG/BCP). "Optimal" serum albumin was defined as $\geq 4.0/3.7$ g/dL ($40/37$ g/L) (BCG/BCP). Nationally, 47% of patients had a mean serum albumin $\geq 4.0/3.7$ g/dL ($40/37$ g/L) (BCG/BCP). 84% of patients had a mean serum albumin $\geq 3.5/3.2$ g/dL ($35/32$ g/L) (BCG/BCP). The percent of patients with mean serum albumin defined as either "adequate" or "optimal" by gender, race, ethnicity, age, diagnosis, duration of dialysis, access type, and mean delivered spKt/V and hemoglobin categories is shown in Table 25. Figure 67 shows the percent of pediatric patients with mean serum albumin $\geq 4.0/3.7$ g/dL ($40/37$ g/L) and $\geq 3.5/3.2$ g/dL ($35/32$ g/L) (BCG/BCP) by age group. The percent of patients with mean serum albumin $\geq 4.0/3.7$ g/dL ($40/37$ g/L) (BCG/BCP) tended to be higher for patients dialyzing less than 6 months compared to patients dialyzing longer 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.

TABLE 25: Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin values $\geq 4.0/3.7$ g/dL (BCG/BCP)^a, and $\geq 3.5/3.2$ g/dL (BCG/BCP), by patient characteristics, October-December 2002. 2003 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	47	84
GENDER		
Males	54	86
Females	38	82
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	*	88
Black	44	81
White	49	86
Other/Unknown	48	86
ETHNICITY		
Hispanic	51	89
Non-Hispanic	46	83
AGE GROUP (years)		
0-4	*	74
5-9	40	81
10-14	41	82
15 to < 18	54	87
DURATION of DIALYSIS (years)		
< 0.5	32	72
0.5-0.9	52	86
1.0-1.9	53	88
2.0-2.9	53	90
3.0-3.9	59	89
4.0+	43	84
ACCESS TYPE		
AV Fistula	60	91
AV Graft	50	90
Catheter	40	79
Catheter ≥ 90 days	42	81
MEAN spKt/V		
≥ 1.2	47	86
< 1.2	48	73
MEAN Hgb (g/dL)		
≥ 11	56	92
< 11	31	72

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

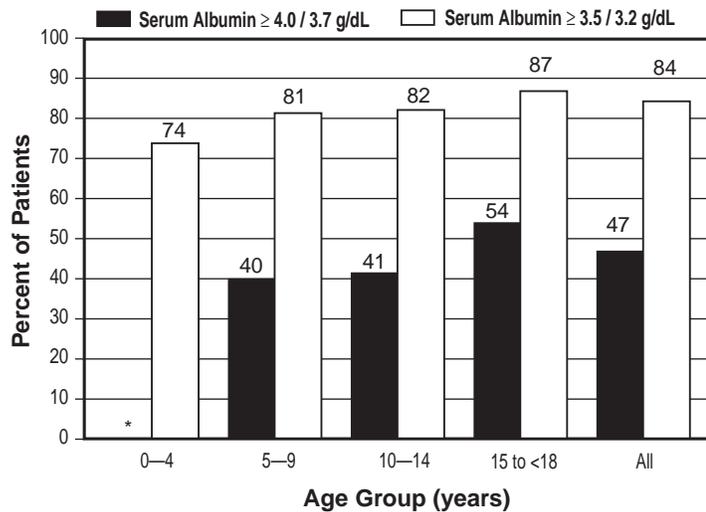
*Value suppressed because $n \leq 10$.

^aBCG/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 67: Percent of all 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), by age, October-December 2002. 2003 ESRD CPM Project.

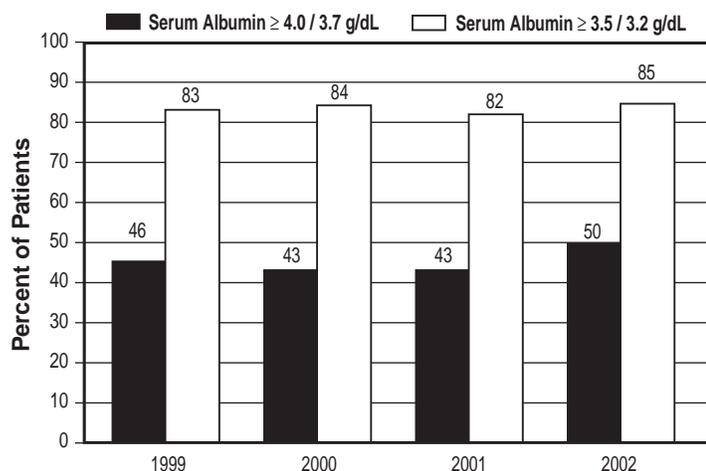


[^]BCG/BCP = bromcresol green/bromcresol purple laboratory methods.
 Note: To convert serum albumin conventional units of g/dL to SI units (g/L), multiply by 10.
 *Value suppressed because n \leq 10.

2. Findings for October-December 2002 compared to previous study periods (for patients 12 to <18 years)

There was no clinically important change or improvement in the percent of pediatric aged 12 to < 18 years in-center hemodialysis patients achieving either “adequate” or “optimal” mean serum albumin levels from late 1999 to late 2002 (FIGURE 68).

Figure 68: Percent of pediatric (aged ≥ 12 to < 18 years) in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ g/dL (BCG/BCP)[^] and $\geq 3.5/3.2$ g/dL (BCG/BCP), October-December 2002 compared to previous study periods. 2003 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.