

2002 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 2002



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 2001

Data on adult peritoneal dialysis patients are from October 2001–March 2002

Data on pediatric in-center hemodialysis patients are from October–December 2001

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Note: The clinical data collected for the 2002 ESRD Clinical Performance Measures Project were from the time period of October–December 2001 for the in-center hemodialysis patients and October 2001–March 2002 for the adult peritoneal dialysis patients.

2003 Data Collection Effort

In 2003, 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 5 & 6).

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 eighteen ESRD Network Organizations throughout the United States (See Appendix 5).
- 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, QI Coordinator, Rick Coffin, Program Analyst, and Janie Hamner, QI Assistant.
- The staff at more than 2,800 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

AV Arterial Venous	HD Hemodialysis
AVF Arterial Venous Fistula	Hgb Hemoglobin
BCG Bromcresol Green Laboratory Method	IV Intravenous
BCP Bromcresol Purple Laboratory Method	K/DOQI Kidney Disease Outcomes Quality Initiative
BMI Body Mass Index	Kt/V or Kt/V_{urea} Urea Clearance x Time/the Volume of distribution of Urea (fractional clearance of urea)
BSA Body Surface Area	NIPD Nightly Intermittent Peritoneal Dialysis
BUN Blood Urea Nitrogen	NKF National Kidney Foundation
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	SLE Systemic Lupus Erythematosus
CrCl Creatinine Clearance	TCV Total Cell Volume
DOQI Dialysis Outcomes Quality Initiative	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	
HCQIP Health Care Quality Improvement Program	

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 2002 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. New this year is the addition of findings for all in-center hemodialysis patients aged < 18 .

The most recent data described in this report are from the 2002 study period which includes the months of October-December 2001 for the in-center hemodialysis patients and October 2001-March 2002 for the peritoneal dialysis patients. This report also compares the 2002 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 9 and 10 (pages 99 and 101) 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 2001, your facility's data that you calculate and enter on this form can be from any time period (national peritoneal dialysis findings are from the time period October 2001 – March 2002). Appendix 8 provides you with over 25 network level hemodialysis findings that you can use to record on your Outcomes Comparison Tool (Appendix 9). 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 13, 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 2002 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 2003.

While significant improvements in care have occurred, the opportunities to improve care for dialysis patients in the U.S. in the area 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 2002 ESRD CPM Project may be found on the following pages:

Adult in-center hemodialysis patients, page 10

Adult peritoneal dialysis patients, page 11

Pediatric in-center hemodialysis patients, page 12

Hemodialysis Adequacy Trends

Figure 2: Percent of adult in-center hemodialysis patients with mean delivered calculated, single session Kt/V ≥ 1.2 in October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.

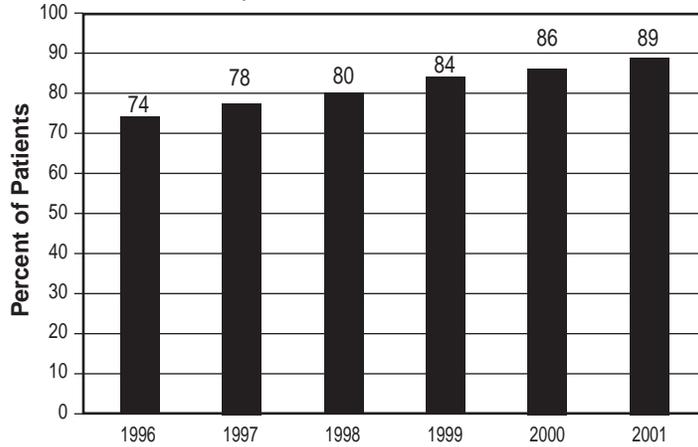
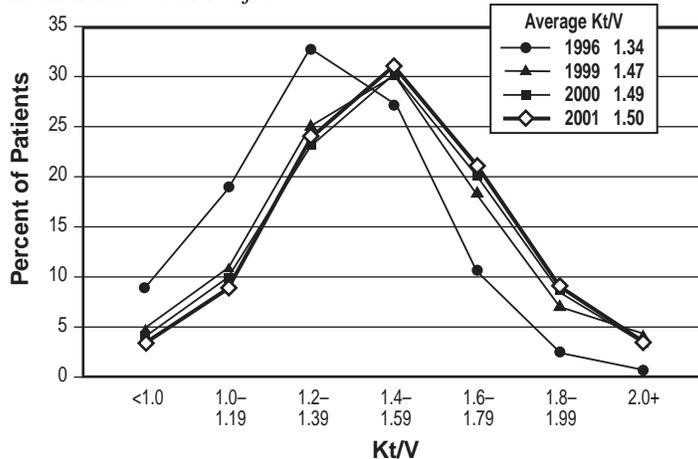
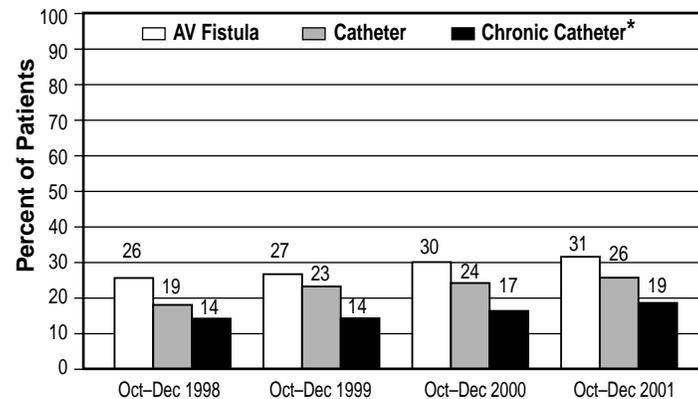


Figure 3: Distribution of mean delivered calculated, single session Kt/V values for adult in-center hemodialysis patients, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



Vascular Access Trends

Figure 4: Vascular access type for all adult in-center hemodialysis patients on their last hemodialysis session during the study period. 2002 ESRD CPM Project.



* Chronic catheter defined as use of a catheter access continuously for 90 days or longer.
 Note: AV graft use not depicted in this figure. See Table 8.

Peritoneal Dialysis Adequacy Trends

Figure 5: Distribution of mean weekly Kt/V_{urea} values for adult CAPD patients, October 2001-March 2002 compared to previous study periods. 2002 ESRD CPM Project.

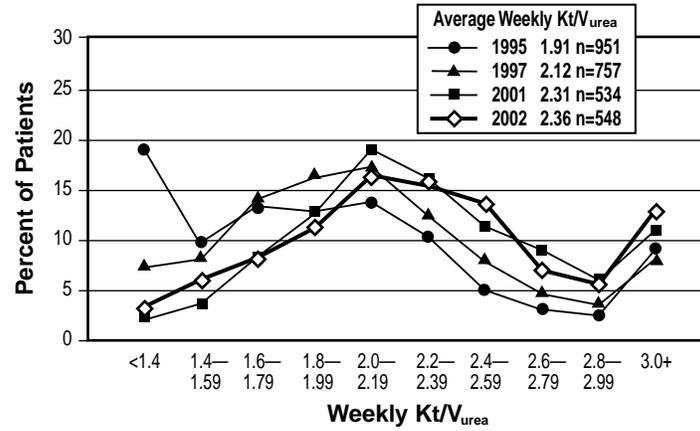


Figure 6: Distribution of mean weekly creatinine clearance values (L/week/1.73m²) for adult CAPD patients, October 2001-March 2002 compared to previous study periods. 2002 ESRD CPM Project.

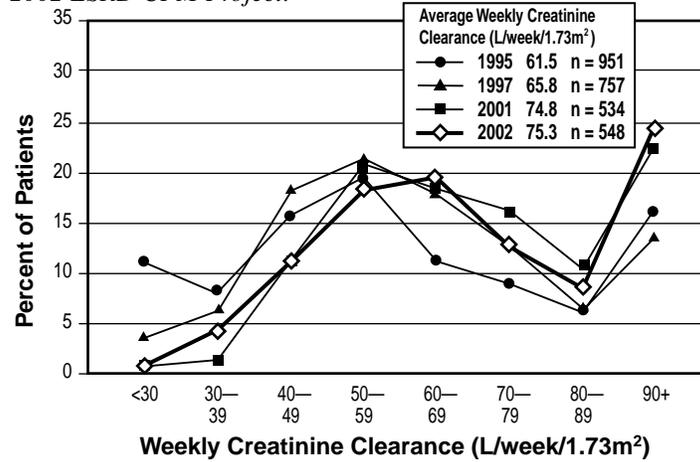
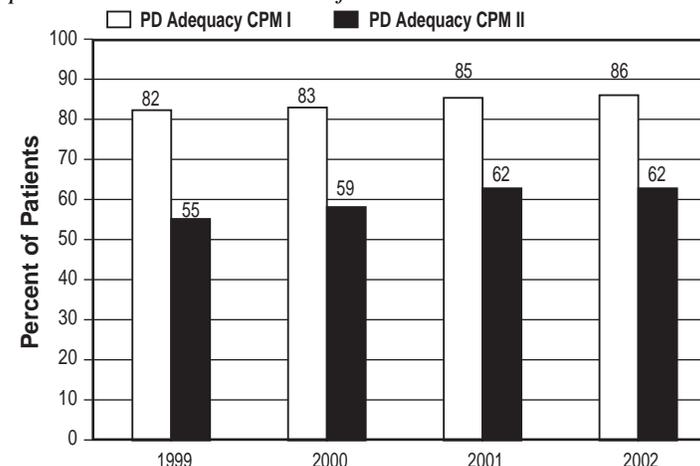


Figure 7: Percent of adult peritoneal dialysis patients with total solute clearance for urea and creatinine measured at least once during the study period (PD Adequacy CPM I) and with total solute clearance calculated in a standard way* (PD Adequacy CPM II), October 2001-March 2002 compared to previous study periods. 2002 ESRD CPM Project.



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

Anemia Management Trends

Figure 8: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.

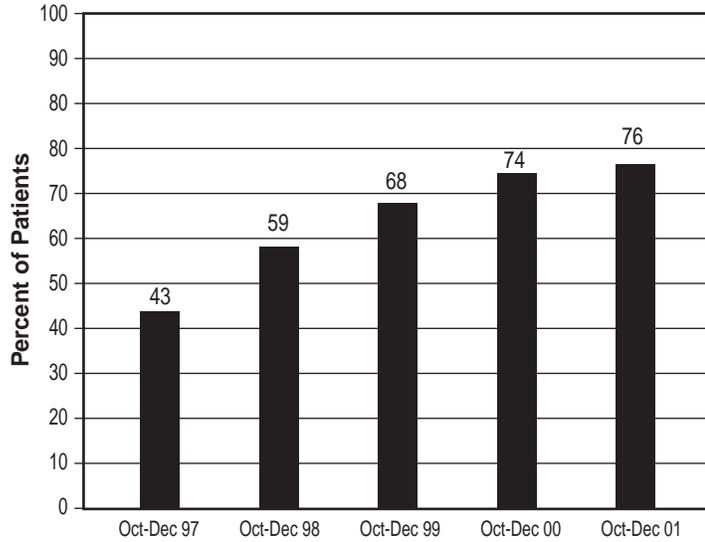


Figure 10: Percent of adult peritoneal dialysis patients with mean hemoglobin ≥ 11 gm/dL, October 2001-March 2002 compared to previous study periods. 2002 ESRD CPM Project.

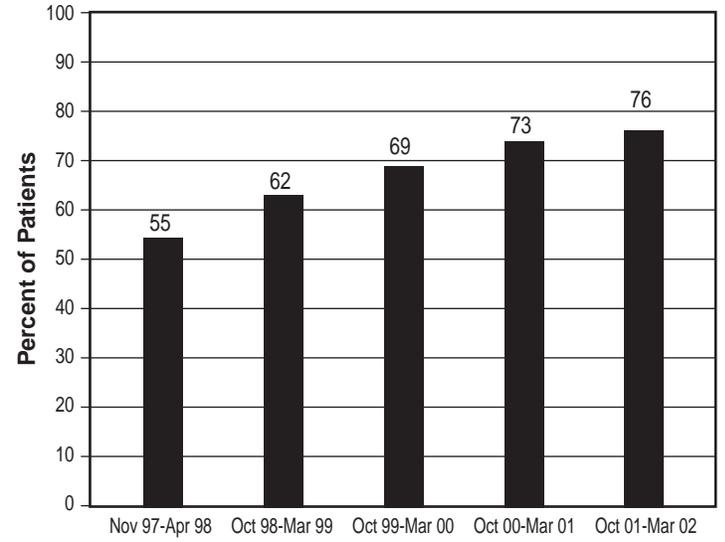


Figure 9: Distribution of mean hemoglobin values for adult in-center hemodialysis patients, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.

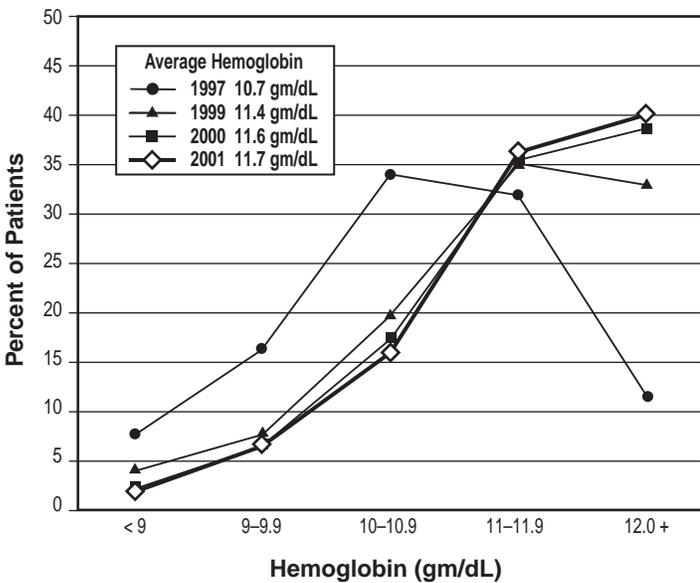
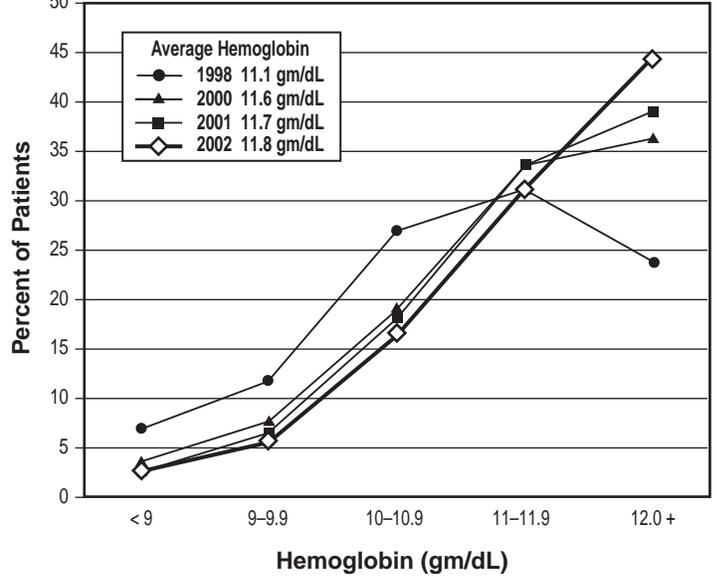


Figure 11: Distribution of mean hemoglobin values for adult peritoneal dialysis patients, October 2001-March 2002 compared to previous study periods. 2002 ESRD CPM Project.



Pediatric Dialysis Trends

Figure 12: Distribution of mean delivered calculated, single session Kt/V values for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients. 2002 ESRD CPM Project.

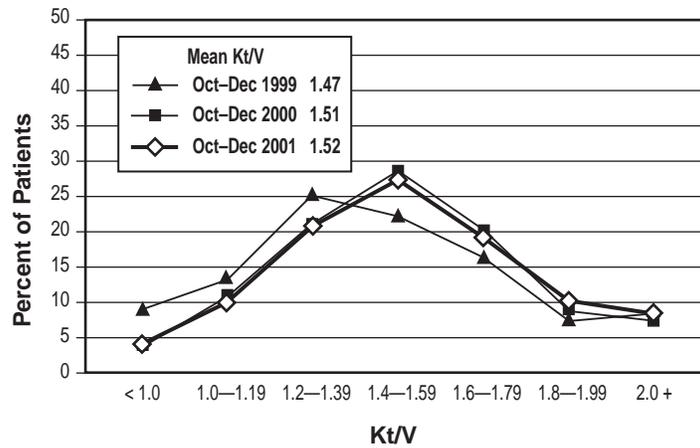


Figure 13: Vascular access type for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period. 2002 ESRD CPM Project.

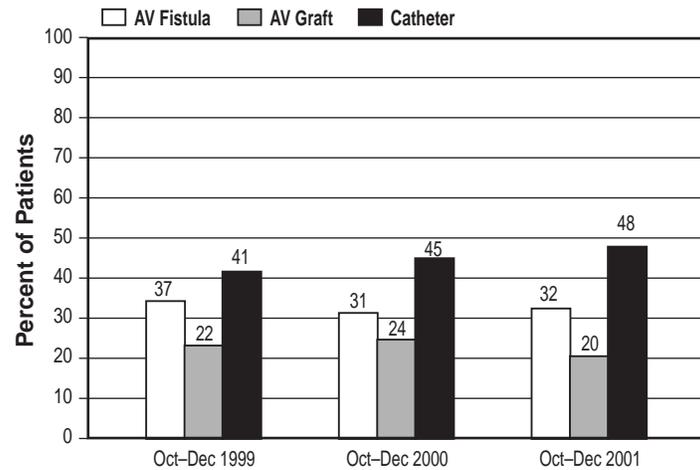
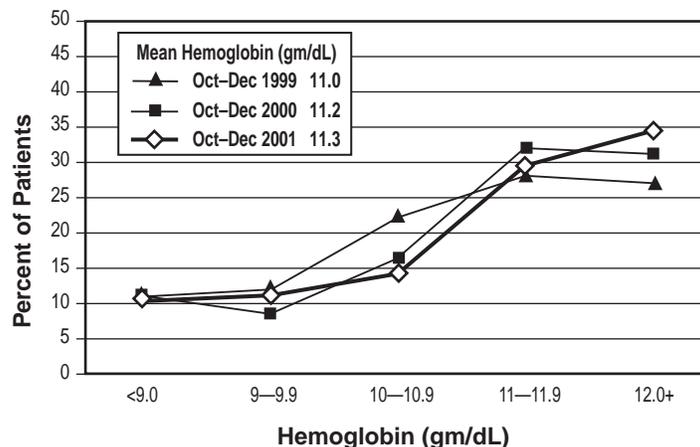


Figure 14: Distribution of mean hemoglobin values for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients. 2002 ESRD CPM Project.



HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2002 ESRD CPM DATA

Adult In-Center Hemodialysis Patients

The data are from October-December 2001:

Hemodialysis Adequacy

- 82% of patients had monthly adequacy measurements performed (HD Adequacy CPM I)
- 68% of patients had their delivered Kt/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 Kt/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 Kt/V ≥ 1.2 (FIGURE 2)
- Median Kt/V was 1.49
- 84% of patients had a mean URR $\geq 65\%$
- Median URR was 71.5%
- Median dialysis session length was 212 minutes

Vascular Access

- 29% of incident patients were dialyzed using an AV fistula (AVF) (Vascular Access CPM I) (FIGURE 32)
- 31% of prevalent patients were dialyzed using an AVF (Vascular Access CPM I) (FIGURE 4)
- 19% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer (Vascular Access CPM II) (FIGURE 4)
- 51% of prevalent patients with an AV graft were routinely monitored for the presence of stenosis (Vascular Access CPM III)

Anemia Management

- 38% of targeted patients prescribed Epoetin had a hemoglobin between 11.0-12.0 gm/dL (Anemia Management CPM I)
- 92% of patients who met the inclusion criteria¹ had at least one documented transferrin saturation value and one documented serum ferritin concentration value (Anemia Management CPM IIa)
- 75% of patients who met the inclusion criteria¹ had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration ≥ 100 ng/mL (Anemia Management CPM IIb)
- 77% of patients who met the inclusion criteria¹ were prescribed intravenous iron in at least one month during the study period (Anemia Management CPM III)
- 76% of patients had a mean hemoglobin ≥ 11 gm/dL (FIGURE 8)
- 8% of patients had a mean hemoglobin < 10.0 gm/dL
- Median hemoglobin was 11.7 gm/dL
- Median weekly IV Epoetin dose was 199.1 units/kg/week
- Median weekly SC Epoetin dose was 167.2 units/kg/week

Serum Albumin

- 36% of patients had a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)² (FIGURE 47)
- 82% of patients had a mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) (FIGURE 47)
- Median serum albumin was 3.8/3.6 gm/dL (BCG/BCP)

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

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

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2002 ESRD CPM DATA

Adult Peritoneal Dialysis Patients

The data are from October 2001-March 2002:

Peritoneal Dialysis Adequacy

- 86% of patients had at least one measured total solute clearance for urea and creatinine (PD Adequacy CPM I) during the six month study period (FIGURE 7)
- 62% of patients had their total solute clearance for urea and creatinine calculated in a standard way¹ (PD Adequacy CPM II) (FIGURE 7)
- 68% of CAPD patients had a mean weekly Kt/V_{urea} of ≥ 2.0 and a mean weekly creatinine clearance $\geq 60L/week/1.73m^2$ OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.(PD Adequacy CPM III) (FIGURE 56)
- 70% of Cycler patients with a daytime dwell had a mean weekly Kt/V_{urea} of ≥ 2.1 and a mean weekly creatinine clearance $\geq 63 L/week/1.73m^2$ OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.(PD Adequacy CPM III) (FIGURE 56)
- 61% of Cycler patients without a daytime dwell had a mean Kt/V_{urea} of ≥ 2.2 and a mean weekly creatinine clearance $\geq 66 L/week/1.73m^2$ OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.(PD Adequacy CPM III) (FIGURE 56)
- Median weekly Kt/V_{urea} for CAPD patients was 2.27
- Median weekly Kt/V_{urea} for Cycler patients with a daytime dwell was 2.25
- Median weekly Kt/V_{urea} for Cycler patients without a daytime dwell was 2.29

Anemia Management

- 36% of targeted patients prescribed Epoetin had a mean hemoglobin between 11.0-12.0 gm/dL (Anemia Management CPM I)
- 74% 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 (Anemia Management CPM IIa)
- 76% of patients who met the inclusion criteria² had at least one transferrin saturation $\geq 20\%$ and one serum ferritin concentration ≥ 100 ng/mL (Anemia Management CPM IIb)
- 31% of patients who met the inclusion criteria² were prescribed intravenous iron in at least one of the two-month periods during the study period (Anemia Management CPM III)
- 76% of patients had a mean hemoglobin ≥ 11 gm/dL (FIGURE 10)
- Median hemoglobin was 11.8 gm/dL
- Median weekly SC Epoetin dose was 119.1 units/kg/week
- Median weekly IV Epoetin dose was 146.9 units/kg/week

Serum Albumin

- 19% of patients had a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)³ (FIGURE 62)
- 61% of patients had a mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) (FIGURE 62)
- Median serum albumin was 3.6/3.3 gm/dL (BCG/BCP)

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.

HIGHLIGHTS FROM THE NATIONAL FINDINGS FOR THE 2002 ESRD CPM DATA

Pediatric In-Center Hemodialysis Patients (aged < 18)¹

The data are from October-December 2001:

Hemodialysis Adequacy

- 87% of patients had a mean delivered calculated, single session adequacy dose of Kt/V \geq 1.2 calculated using the Daugirdas II formula (6) (TABLE 23)
- Median Kt/V was 1.54
- Median dialysis session length was 201 minutes

Vascular Access

- 26% of prevalent patients were dialyzed using an AV fistula (AVF) (TABLE 24)
- 46% of prevalent patients were dialyzed with a chronic catheter continuously for 90 days or longer
- 48% of prevalent patients with an AVF or an AV graft were routinely monitored for the presence of stenosis

Anemia Management

- 62% of patients had a mean hemoglobin \geq 11 gm/dL (TABLE 26)
- Median hemoglobin was 11.4 gm/dL
- Median weekly IV Epoetin dose was 278.9 units/kg/week

Serum Albumin

- 41% of patients had a mean serum albumin \geq 4.0/3.7 gm/dL (BCG/BCP)² (FIGURE 75)
- 82% of patients had a mean serum albumin \geq 3.5/3.2 gm/dL (BCG/BCP) (FIGURE 75)
- Median serum albumin was 3.9/3.5 gm/dL (BCG/BCP)

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 2003, 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 315 per million population (7). As of December 31, 2001, there were 285,982 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 2002 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 2001 and adult peritoneal dialysis patients for the time period October 2001–March 2002.

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. It 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 fourth data collection effort for the ESRD CPMs which was conducted in 2002 and collected data from October–December 2001 for adult and pediatric in-center hemodialysis patients, and from October 2001–March 2002 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 2002, a listing of adult (aged ≥ 18 years as of September 30, 2001) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 2001, 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, 2001. The final sample consisted of 8,863 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 1,451 peritoneal dialysis patients.

All pediatric (aged < 18 years) in-center hemodialysis patients in the U.S. ($n = 710$) were included in the 2002 ESRD CPM Study.

Data Collection

Three data collection forms were used: a three-page in-center hemodialysis form, a four-page peritoneal dialysis form, and a one-page hemodialysis facility-specific form (Appendices 2, 3, and 4 respectively); 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 2002, 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 2001. 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 2001, December 2001–January 2002, and February–March 2002.

Completed forms were returned to the appropriate Network, where data were reviewed for acceptability and manually entered into a Visual FoxPro data entry program. In August 2002, each Network sent a copy of their Visual FoxPro data files to CMS's contractor, ESRD Network 9/10 in Indianapolis, Indiana, where the data were aggregated and then submitted to CMS, in an Epi Info, v.6.04a file (23), for the initial analysis.

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 15 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 Kt/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 $Kt/V \geq 1.2$.

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 Kt/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 arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of 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 gm/dL. Patients with a mean hemoglobin >12 gm/dL and not prescribed Epoetin were excluded from analysis for this CPM.
- IIa. For anemic patients (hemoglobin < 11 gm/dL 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 gm/dL 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 gm/dL 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 gm/dL and < 10 gm/dL 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 for the first time during this data collection period. All monthly recorded data were used in determining the percent of patients prescribed Epoetin or Darbepoetin. A "held" dose of Epoetin was entered as "zero" units. A "held" dose of Darbepoetin was entered as "zero" micrograms. These zero values were included in the calculation of the mean weekly Epoetin or Darbepoetin doses. The average prescribed weekly Epoetin doses (units/kg/week) were stratified by hemoglobin values.

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

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

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 (24).

For the history of this project, mean serum albumin values < 3.5 gm/dL by the BCG method have been defined as an indicator of inadequate serum albumin. Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we have historically also defined a BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. Mean serum albumin values ≥ 4.0 gm/dL (BCG method) and ≥ 3.7 gm/dL (BCP method) 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 gm/dL for the bromocresol green method) is the outcome goal (25).

Findings from this project allow us to report the percent of patients with mean serum albumin values ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method) and the percent of patients with mean serum albumin values ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (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 2001 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 Kt/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 8,399 of the 8,863 patients from the sample (response rate = 95%) (TABLE 1).

Characteristics regarding the gender, race, ethnicity, age, diagnosis, and duration of dialysis (years) of ESRD for these patients are shown in Table 2. As expected, the characteristics of this random sample were very similar to the characteristics of the overall US hemodialysis population (7). Data regarding Epoetin use, serum ferritin concentrations, transferrin saturation levels, iron use, dialyzer KUF (a measure of fluid removal), 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 (26, 27).

For this report, each patient's mean value for the three-month project period was determined from the available data for the following items: Kt/V (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 route of administration, 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 2001, sample size and response rate for the 2002 ESRD CPM Project.

Network	# HD Patients Dec 2001	Sample Size	# Acceptable Forms [^]	Response Rate %
1	8,921	486	454	93.4
2	19,217	497	466	93.8
3	11,632	491	419	85.3
4	12,293	493	455	92.3
5	15,337	495	482	97.4
6	23,843	499	488	97.8
7	14,929	495	483	97.6
8	14,768	494	480	97.2
9	17,862	496	472	95.2
10	11,183	490	442	90.2
11	15,415	495	470	94.9
12	9,867	488	434	88.9
13	11,068	490	480	98.0
14	21,360	497	486	97.8
15	10,859	490	470	95.9
16	6,216	477	468	98.1
17	13,058	493	467	94.7
18	19,378	497	483	97.2
Total	257,206	8,863	8,399	94.8

[^] 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 2001 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 82% of patients.

TABLE 2: Characteristics of adult in-center hemodialysis patients in the 2002 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 2000.

Patient Characteristic	2002 CPM Sample for Analysis		All US in 2000*	
	# [^]	%	# in 1000s	%
TOTAL	8399	100	244.4	100
GENDER				
Men	4431	53	129.8	53
Women	3967	47	114.5	47
RACE				
American Indian/ Alaska Native	161	2	4.2	2
Asian/Pacific Islander	338	4	9.3	4
Black	3135	37	94.9	39
White	4473	53	131.3	54
Other/Unknown	292	3	4.8	2
ETHNICITY				
Hispanic	1008	12	29.3	12
Non-Hispanic	7247	86	215.1	88
Other/Unknown	144	2	0	0
AGE GROUP (years)				
18-49	2012	24	57.2**	23
50-59	1599	19	47.3	19
60-64	936	11	27.1	11
65-69	1030	12	29.8	12
70-79	1990	24	57.2	23
80+	831	10	24.5	10
DIAGNOSIS				
Diabetes mellitus	3599	43	100.3	41
Hypertension	2116	25	67.4	28
Glomerulonephritis	955	11	27.8	11
Other/Unknown	1729	21	48.9	20
DURATION of DIALYSIS (years)				
<0.5	1025	12		
0.5-0.9	1158	14		
1.0-1.9	1551	19		
2.0+	4607	55		

*USRDS: 2002 Annual Data Report, Bethesda, MD, National Institutes of Health, 2002. Tables D.5 and D.7

[^] Subgroup totals may not equal 8,399 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 2001–March 2002. Of the 1,451 patients sampled, 1,352 patients were included in the sample for analysis (93% response rate) (TABLE 3). Selected patient characteristics of this sample for analysis are shown in Table 4.

For this report, each patient's mean value for the six-month study period was determined from available data for the following items: weekly Kt/V_{urea}, weekly creatinine clearance, hemoglobin, serum albumin, prescribed Epoetin or Darbepoetin dose and route of administration, serum ferritin concentrations, and transferrin saturation levels. 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 2001, sample size and response rate for the 2002 ESRD CPM Project.

Network	# Peritoneal Dialysis Patients in December 2001	Sample Size	# Acceptable Forms [^]	Response Rate %
1	1151	56	50	89.3
2	1487	89	73	82.0
3	1259	69	55	79.7
4	919	55	46	83.6
5	1577	94	92	97.9
6	2360	128	127	99.2
7	1285	60	60	100.0
8	1591	86	81	94.2
9	2271	129	118	91.5
10	1081	67	58	86.6
11	1747	108	104	96.3
12	1406	77	69	89.6
13	1005	57	57	100.0
14	1784	98	95	96.9
15	1144	60	58	96.7
16	905	51	50	98.0
17	1530	68	61	89.7
18	1884	99	98	98.9
Total	26,386	1,451	1,352	93.2

[^] 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 2002 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 2000.

Patient Characteristic	2002 CPM Sample for Analysis		All US in 2000*	
	# [^]	%	# in 1000s	%
TOTAL	1352	100	23.7	100
GENDER				
Men	676	50	12.1	51
Women	676	50	11.6	49
RACE				
American Indian/ Alaska Native	25	2	0.3	1.5
Asian/Pacific Islander	61	5	1.2	5
Black	361	27	6.2	26
White	863	64	15.5	65
Other/Unknown	42	3	0.5	2
ETHNICITY				
Hispanic	161	12	2.7	11
Non-Hispanic	1172	87	21.0	89
Other/Unknown	19	1	0	0
AGE GROUP (years)				
18-49	521	39	8.2**	35
50-59	287	21	5.3	22
60-64	132	10	2.4	10
65-69	132	10	2.4	10
70-79	220	16	3.6	15
80+	59	4	0.9	4
DIAGNOSIS				
Diabetes mellitus	463	34	8.3	35
Hypertension	297	22	5.2	22
Glomerulonephritis	233	17	4.5	19
Other/Unknown	359	27	5.7	24
DURATION of DIALYSIS (years)				
<0.5	320	24		
0.5-0.9	177	13		
1.0-1.9	273	20		
2.0+	574	43		

*USRDS: 2002 Annual Data Report, Bethesda, MD, National Institutes of Health, 2002. Tables D.5 and D.7.

[^] Subgroup totals may not equal 1352 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 710 patients, 668 patients were included in the sample for analysis (94% 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: Kt/V, dialysis session length, dialyzer K_Uf, 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 period: October–December 2001 for the adult in-center hemodialysis patients, and October 2001–March 2002 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 2001 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 2002 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 2002 ESRD CPM Project.

Patient Characteristic	2002 CPM Project	
	# ^a	%
TOTAL	668	(100)
GENDER		
Males	380	(57)
Females	287	(43)
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	16	(2)
Black	263	(39)
White	322	(48)
Other/Unknown	59	(9)
ETHNICITY		
Hispanic	172	(26)
Non-Hispanic	482	(72)
Other/Unknown	14	(2)
AGE GROUP (years)		
0-4	34	(5)
5-9	66	(10)
10-14	223	(33)
15 to <18	345	(52)
DIAGNOSIS		
Congenital/Urologic	179	(27)
FSGS	99	(15)
Glomerulonephritis	93	(14)
SLE	28	(4)
Cystic Disease	19	(3)
Hypertension	18	(3)
Other/Unknown	232	(35)
DURATION of DIALYSIS (years)		
<0.5	115	(17)
0.5-0.9	110	(17)
1.0-1.9	126	(19)
2.0+	306	(46)

^aSubgroup totals may not equal 668 due to missing data.

*Value suppressed because n ≤ 10.

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 2001 for the following items: 1) hemoglobin; 2) paired pre- and post-dialysis BUN values; and 3) serum albumin value.

Two or more monthly values for these clinical measures were available for 93% of patients for hemoglobin and 93% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 84% 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 90%. Monthly paired pre- and post-dialysis BUN values were available for 74% of patients.

ADULT IN-CENTER HEMODIALYSIS PATIENTS OCTOBER-DECEMBER 2001

SYNOPSIS

- Purpose of Project: The ultimate purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in improving the care provided to ESRD patients. The specific purposes of the 2002 project were:

To compare the prevalence of important clinical measures and/or characteristics of adult (aged ≥ 18 years) in-center hemodialysis patients in the US in October–December 2001 to the prevalence of those characteristics in the last quarter of each year (October–December) 1993 through 2000;

AND, to identify opportunities to improve care for those patients.

- Method Used: A random sample of adult in-center hemodialysis patients who were alive on December 31, 2001, was selected (sample size 8,863).

ESRD facilities with one or more patients in the sample submitted completed data collection forms to their respective ESRD Network. The Networks then submitted a data file to ESRD Network 9/10 with the clinical information about these patients for the time period October, November, December 2001 for aggregation. This aggregated data file was then forwarded to CMS for initial analysis.

- Initial Findings: The sample for analysis consisted of 8,399 patients which was 95% of the original sample. Highlights from the initial findings are summarized below.

IMPROVEMENT OCCURRED

- 89% of the sampled patients were receiving dialysis with a delivered calculated, single session Kt/V ≥ 1.2 . This was an increase of three percentage points over late 2000 (FIGURE 2).
- 87% of Black patients and 89% of White patients were receiving dialysis with a mean delivered calculated, single

session Kt/V ≥ 1.2 in October–December 2001 (TABLE 7). This was a three percentage point increase for Black patients and a two percentage point increase for White patients from late 2000.

- 76% of patients had a mean hemoglobin ≥ 11 gm/dL in the last quarter of 2001 compared to 74% of the patients in the last quarter of 2000, a two percentage point increase from late 2000 to late 2001 (FIGURE 8).

- 9% of Black patients and 7% of White patients had a mean hemoglobin < 10 gm/dL in October–December 2001 compared to 10% and 8%, respectively, in October–December 2000.

OPPORTUNITIES TO IMPROVE

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

- 71% of incident patients and 69% of all patients were not dialyzed with an AV fistula during their last hemodialysis session October-December 2001.

- 49% of patients with an AV graft did not have this graft routinely monitored for the presence of stenosis during the three month study period.

- 24% of patients did not have a mean hemoglobin ≥ 11 gm/dL during the three month study period.

- 33% of patients prescribed Epoetin did not have a mean hemoglobin of 11–12.9 gm/dL during the three-month study period.

- 64% of patients did not have a mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method) during the three-month study period.

NEXT STEPS:

Network and CMS staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2003, 2004 and beyond. This Annual Report, as well as previous Annual Reports, and Supplemental Reports may be found at www.cms.hhs.gov/esrd/1.asp.

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 2001 (the serum albumin information is not considered a CPM for this report);
- (2) a description of other quality indicators or data analysis for October–December 2001; and
- (3) a comparison of CPM and/or other quality indicators results or findings for October–December 2001 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, 2001, was selected ($n=8863$). 8399 patients (95%) were included in the sample for analysis.

A. ADEQUACY OF HEMODIALYSIS

1. CPM Findings for October–December 2001

Data to assess five hemodialysis adequacy CPMs were collected in 2002. The time period from which these data were abstracted was October–December 2001. Results for three of 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: 82% of adult in-center hemodialysis patients in the sample for analysis had documented measurements of hemodialysis adequacy (URR and/or Kt/V) for each month during the three-month study period (October–December 2001). These measurements were recorded in the patient's chart, not calculated from individual data points. An additional 13% 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 Kt/V) (6).

FINDING: 68% of adult in-center hemodialysis patients in the sample for analysis had each delivered hemodialysis dose reported as Kt/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 $Kt/V \geq 1.2$ using the Daugirdas II formula

(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 ($n=6342$).

FINDING: For the last quarter of 2001, 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 [$n=6342$]) had a mean delivered calculated, single session (hereafter referred to as delivered) hemodialysis dose of $Kt/V \geq 1.2$.

2. Other Hemodialysis Adequacy Findings for October–December 2001

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% ($n=33$) 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 Kt/V of all adult in-center hemodialysis patients in the sample for analysis in the last quarter of 2001 was $1.50 (\pm 0.26)$ (FIGURE 3). The distribution of Kt/V values for these patients is shown in Figure 15. The mean (\pm SD) delivered calculated URR for this sample was 70.9% ($\pm 6.7\%$). 84% of patients had a mean delivered URR $\geq 65\%$. The mean delivered Kt/V and the percent of patients with mean delivered Kt/V ≥ 1.2 and Kt/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 Kt/V measure available ($n=8285$) who received adequate hemodialysis, defined as a mean delivered Kt/V ≥ 1.2 , approximately equivalent to URR $\geq 65\%$ (2) in the last quarter of 2001 was 89% (TABLE 6, FIGURE 2).

The percent of patients receiving hemodialysis with a mean delivered Kt/V ≥ 1.2 was higher for women than for men, higher for Whites than for Blacks, higher for Hispanics than for non-Hispanics, higher for patients dialyzing six months or longer than for patients dialyzing less than six months, higher for patients in lower quintiles of body weight, and higher for patients ≥ 65 years of age than for younger patients (TABLE 6).

A higher percent of patients with mean hemoglobin ≥ 11 gm/dL and mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) had a mean Kt/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 Kt/V ≥ 1.2 compared to patients dialyzed with a catheter (89% and 94% vs. 78% respectively) (TABLE 6).

Figure 15: Distribution of mean delivered calculated, single session Kt/V values for adult in-center hemodialysis patients, October–December 2001. 2002 ESRD CPM Project.

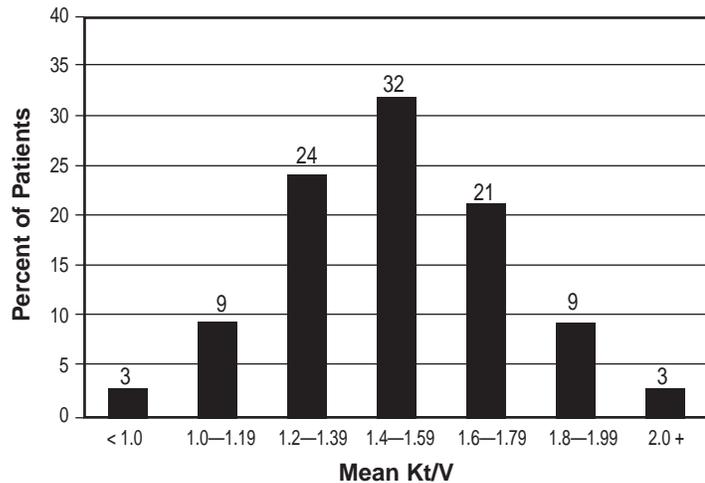
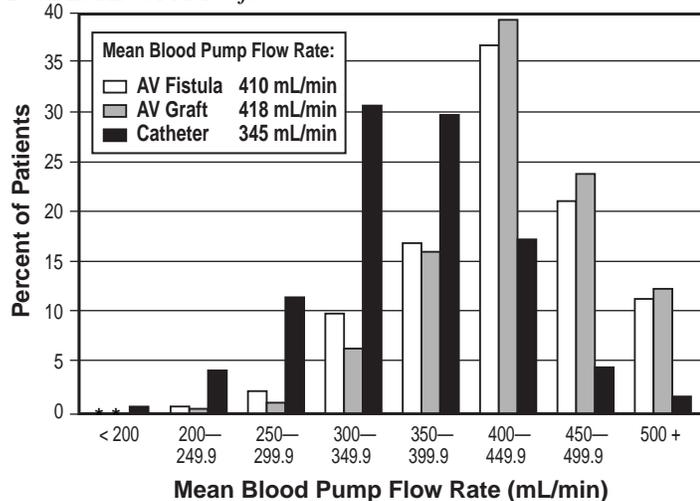


Figure 16: Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for adult in-center hemodialysis patients, by access type, October–December 2001. 2002 ESRD CPM Project.



Note: Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (28). 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 (29).

*Value suppressed because n ≤ 10.

TABLE 6: Mean delivered calculated, single session Kt/V and percent of adult in-center hemodialysis patients with mean delivered calculated, single session Kt/V ≥ 1.2 and ≥ 1.3 by patient characteristics, October–December 2001. 2002 ESRD CPM Project.

Patient Characteristics	Mean Kt/V	% Kt/V ≥ 1.2	%Kt/V ≥ 1.3
TOTAL	1.50	89	79
GENDER			
Men	1.43	85	73
Women	1.57	93	85
RACE			
American Indian/ Alaska Native	1.57	91	85
Asian/Pacific Islander	1.59	94	87
Black	1.46	87	76
White	1.51	89	81
Other/Unknown	1.53	90	81
ETHNICITY			
Hispanic	1.55	91	84
Non-Hispanic	1.49	88	78
AGE GROUP (years)			
18-44	1.46	85	74
45-54	1.46	86	74
55-64	1.47	88	76
65-74	1.52	90	82
75+	1.56	93	86
DIAGNOSIS			
Diabetes mellitus	1.49	88	78
Hypertension	1.49	89	79
Glomerulonephritis	1.51	89	81
Other/Unknown	1.52	89	80
DURATION of DIALYSIS (years)			
< 0.5	1.35	70	57
0.5-0.9	1.47	86	74
1.0-1.9	1.50	91	81
2.0+	1.53	92	84
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)			
32.5-58.7	1.66	96	93
58.8-67.9	1.55	93	85
68.0-76.9	1.48	89	80
77.0-89.6	1.44	87	76
89.7-210.2	1.35	78	61
ACCESS TYPE			
AV Fistula	1.49	89	80
AV Graft	1.55	94	86
Catheter	1.40	78	65
MEAN Hgb (gm/dL)			
≥ 11	1.50	90	81
< 11	1.47	84	73
MEAN SERUM ALBUMIN (gm/dL)			
≥ 3.5/3.2 BCG/BCP*	1.51	90	81
< 3.5/3.2 BCG/BCP	1.45	82	71

* BCG/BCP = bromcresol green/bromcresol purple laboratory methods

The mean (\pm SD) dialysis session length was 217 minutes (\pm 30 minutes). The mean dialysis session length was somewhat longer for men than for women (224 minutes vs. 208 minutes), for Blacks than for Whites (222 minutes vs. 213 minutes), and for patients dialyzing six months or longer compared to patients dialyzing less than six months (218 minutes vs. 209 minutes). Patients in the highest quintile of post-dialysis body weight (kg) had longer dialysis session lengths compared to patients in the lowest quintile (237 minutes vs. 199 minutes). The mean dialysis session length was 218 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 2001.

The mean (\pm SD) delivered blood pump flow rate 60 minutes into the dialysis session was 410 mL/min (\pm 62.3 mL/min) for patients with an AVF, 418 mL/min (\pm 59.4 mL/min) for patients with either a synthetic or bovine graft, and 345 mL/min (\pm 60.5 mL/min) for patients with a catheter access during October - December 2001 (FIGURE 16). Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (28). 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 (29).

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 Kt/V \geq 1.2 in each Network area. The percent of all patients with mean delivered Kt/V \geq 1.2 ranged from 86% to 92% among the 18 Networks (FIGURES 17, 18).

Figure 17: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session Kt/V \geq 1.2, by Network, October–December 2001. 2002 ESRD CPM Project.

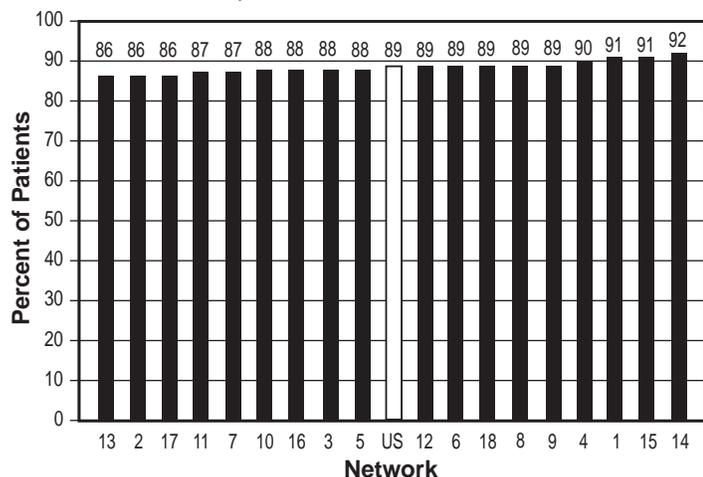
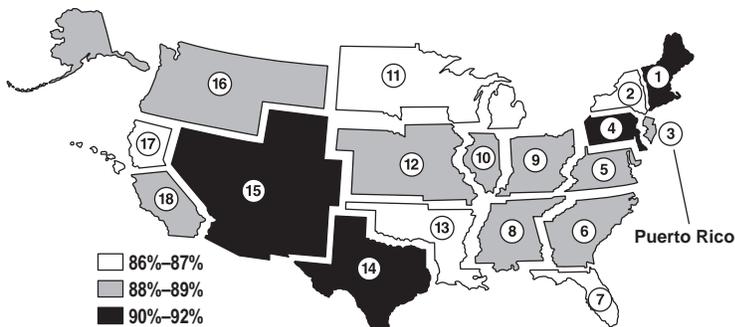


Figure 18: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session Kt/V \geq 1.2, by Network, October–December 2001. 2002 ESRD CPM Project.



3. CPM and other Findings for October-December 2001 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 average (\pm SD) delivered Kt/V in October-December 2001 was 1.50 (\pm 0.26), an increase from previous study years (FIGURE 3). The percent of patients receiving dialysis with a mean delivered Kt/V \geq 1.2 increased significantly from 86% in late 2000 to 89% in late 2001 (FIGURE 2). This significant improvement occurred for both men and women and for White and Black patients (FIGURES 19 and 20).

Figure 19: Percent of adult male in-center hemodialysis patients with mean delivered, single session Kt/V \geq 1.2, by race, October–December 2001 compared to previous study periods. 2002 ESRD CPM Project.

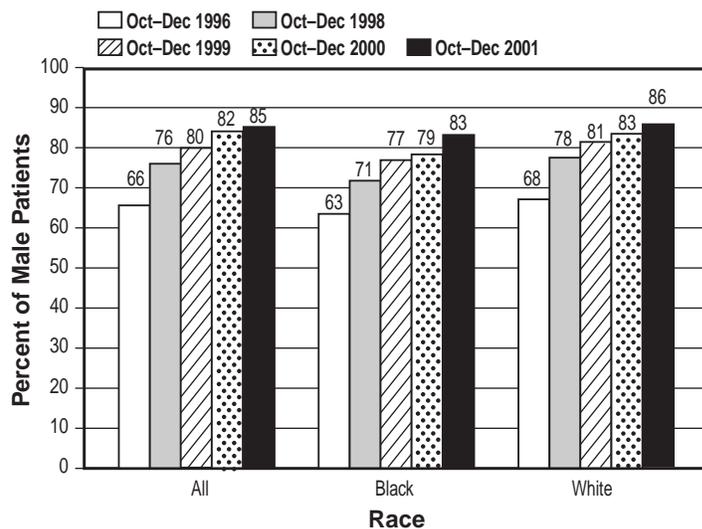


TABLE 7: Percent of adult in-center hemodialysis patients receiving dialysis with a mean delivered, single session Kt/V \geq 1.2, by gender, race, ethnicity and Network, October-December 2001. 2002 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	91	86	88	90	88	89	87	89	89	88	87	89	86	92	91	88	86	89	89	
GENDER																				
Men	89	84	87	86	83	87	84	88	86	81	83	84	79	89	89	84	80	82	85	
Women	93	88	89	94	94	90	91	91	94	94	91	94	93	95	94	92	93	97	93	
RACE																				
Black	92	82	87	91	87	88	86	89	89	82	82	85	87	94	83	79	80	87	87	
White	90	87	89	89	89	91	88	90	90	92	88	91	83	91	92	88	85	88	89	
ETHNICITY																				
Hispanic	92	83	88	92	100	*	84	*	*	97	*	92	81	94	94	91	88	93	91	
Non-Hispanic	90	86	88	90	88	89	88	90	90	87	87	89	86	91	90	88	85	87	88	

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

* Value suppressed because $n \leq 10$.

Figure 20: Percent of adult female in-center hemodialysis patients with mean delivered, single session Kt/V ≥ 1.2, by race, October–December 2001 compared to previous study periods. 2002 ESRD CPM Project.

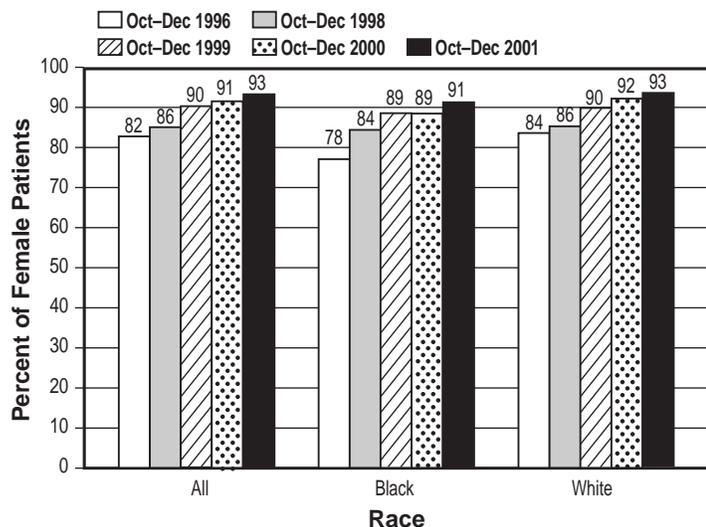
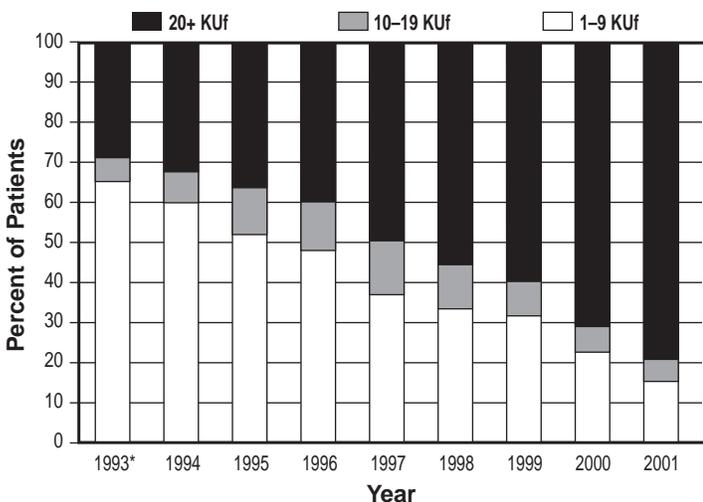


Figure 21 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer Kuf category October–December 2001, compared to previous study years. The percent of patients dialyzed with a dialyzer with a Kuf ≥ 20 mL/mmHg/hr increased from approximately 30% in late 1993 to approximately 80% in late 2001.

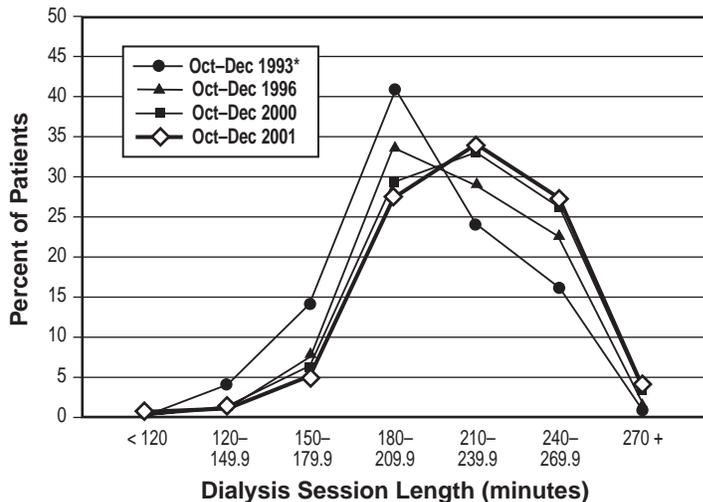
Figure 21: Percent of adult in-center hemodialysis patients dialyzed by dialyzer Kuf category, October–December 2001 compared to previous study periods. 2002 ESRD CPM Project.



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

Figure 22 shows a trend for slight increases in dialysis session lengths from late 1993 to late 2001.

Figure 22: Distribution of mean dialysis session length (minutes), October–December 2001 compared to previous study periods. 2002 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.

B. VASCULAR ACCESS

1. CPM Findings for October-December 2001

Data to assess three vascular access CPMs were collected in 2002. The time period from which these data were abstracted was October–December 2001. Results for these CPMs are included in this report.

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

FINDING: 29% of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 2001 and August 31, 2001, [n = 1536]) were dialyzed using an AVF on their last hemodialysis session during October–December 2001.

31% of all patients in the sample for analysis were dialyzed using an AVF during their last hemodialysis session October–December 2001.

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: 19% of all patients in the sample for analysis were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 2001.

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: 51% of patients with an AV graft (n=3539) had this graft routinely monitored for the presence of stenosis during October–December 2001.

TABLE 8: Vascular access type for incident^a and all adult in-center hemodialysis patients during the last hemodialysis session of the study period, by selected patient characteristics, October-December 2001. 2002 ESRD CPM Project.

Patient Characteristic	Incident (n=1536)			Prevalent (n=8399)		
	AVF %	Graft %	Catheter %	AVF %	Graft %	Catheter %
TOTAL	29	35	36	31	43	26
GENDER						
Men	39	30	31	41	37	22
Women	17	41	42	20	51	30
RACE						
American Indian/ Alaska Native	63	*	*	47	31	22
Asian/Pacific Islander	36	36	27	35	46	19
Black	23	43	34	27	49	24
White	29	32	39	33	39	28
Other/Unknown	44	*	32	35	39	26
ETHNICITY						
Hispanic	30	37	34	32	47	21
Non-Hispanic	28	35	37	31	43	26
AGE GROUP (years)						
18-44	40	29	30	41	35	24
45-54	32	33	35	36	41	23
55-64	30	33	37	31	45	24
65-74	27	39	35	26	49	25
75+	19	39	42	24	45	31
DIAGNOSIS						
Diabetes Mellitus	25	41	34	27	47	26
Hypertension	30	32	39	32	44	24
Glomerulonephritis	40	30	30	40	38	22
Other/Unknown	31	28	42	33	39	29
DURATION of DIALYSIS (years)						
< 0.5	21	29	50	18	23	59
0.5-0.9	31	38	31	31	38	31
1.0-1.9	N/A	N/A	N/A	33	43	24
2.0+	N/A	N/A	N/A	33	50	18

^aAn incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2001 and August 31, 2001.

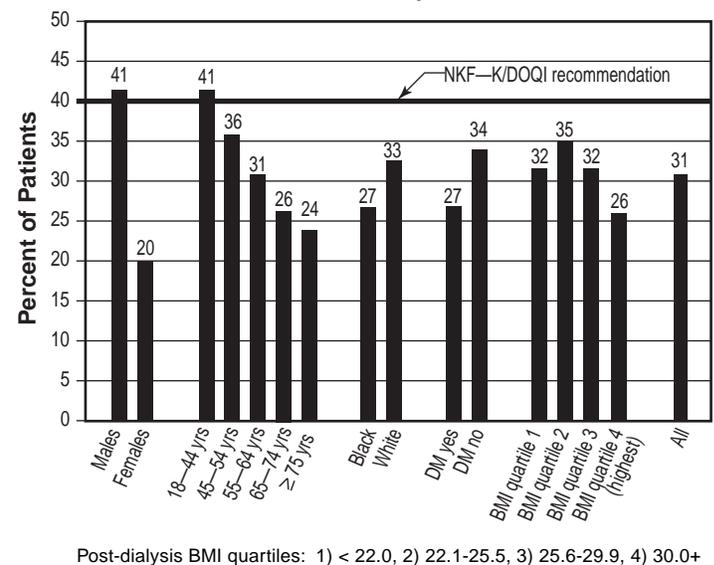
Note: Percentages may not add up to 100% due to rounding.

*Value suppressed because n ≤ 10.

2. Other Vascular Access Findings for October-December 2001

29% of incident and 31% of prevalent patients in the sample for analysis were dialyzed with an AVF on their last hemodialysis session during October–December 2001 (TABLE 8). More men,

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 2001, by patient characteristics. 2002 ESRD CPM Project.



Whites, patients 18-44 years old, patients with causes of ESRD other than diabetes mellitus, and patients dialyzing six months or longer were dialyzed with an AVF compared to women, Blacks, 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 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) (FIGURE 23). The percent of prevalent patients with a catheter as their vascular access, by several patient characteristics, is shown in Figure 24. 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.

19% of patients were dialyzed with a catheter for 90 days or longer (defined for this report as chronic catheter use). 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 25). All patient groups examined did not meet the current NKF-K/DOQI recommendation of less than 10% of chronic hemodialysis patients with a catheter as their vascular access.

There was wide geographic variation in the percent of all patients dialyzed with an AVF; the percent ranged from 23% to 46% among the 18 Network areas (FIGURE 26, TABLE 9). This geographic variation in AVF use was also noted for incident patients, ranging from 13% to 49% among the 18 Network areas (FIGURE 27).

The percent of patients dialyzed with a catheter exhibited geographic variation, ranging from 17% to 36% among the 18 Network areas (FIGURE 28, TABLE 10). Chronic catheter use ranged from 13% to 30% across the 18 Network areas (FIGURE 29).

Figure 24: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 2001, by patient characteristics. 2002 ESRD CPM Project.

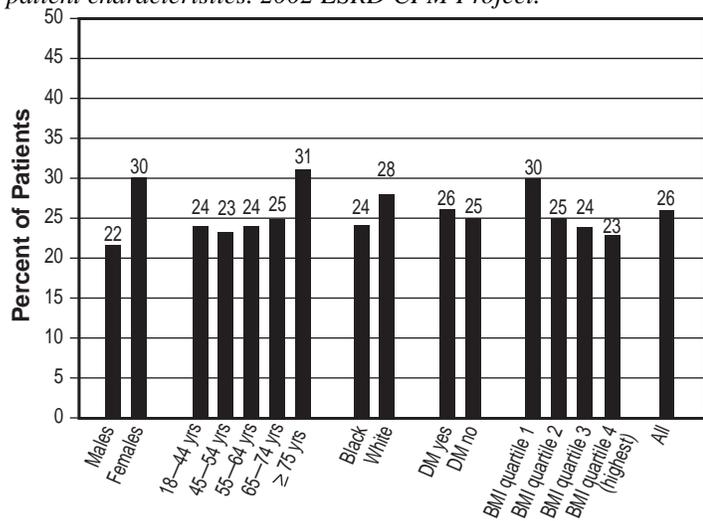


Figure 25: Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October–December 2001, by patient characteristics. 2002 ESRD CPM Project.

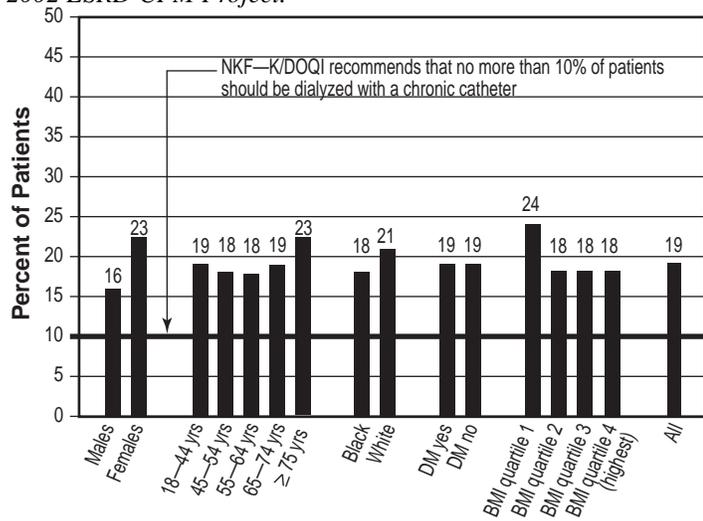


Figure 26: Percent of all adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 2001, by Network. 2002 ESRD CPM Project.

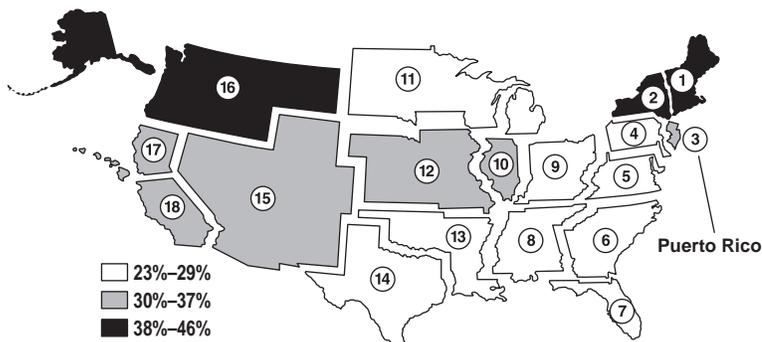
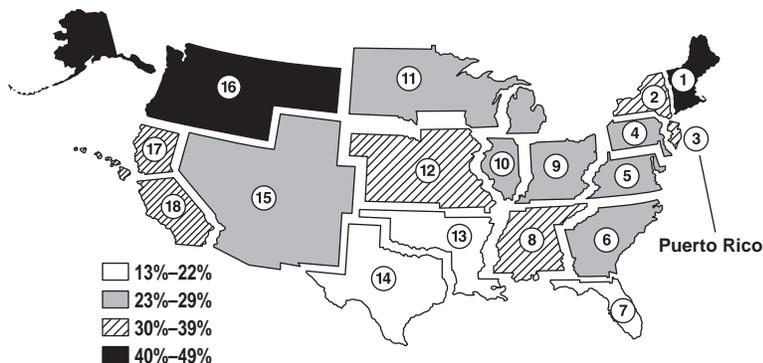


Figure 27: Percent of incident* adult in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 2001, by Network. 2002 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2001 and August 31, 2001.

Figure 28: Percent of all adult in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 2001, by Network. 2002 ESRD CPM Project.

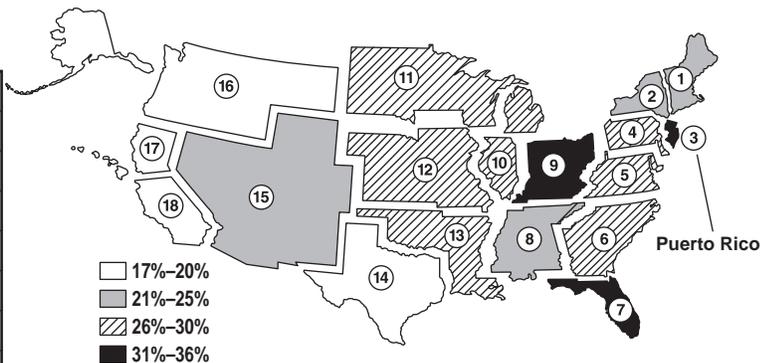


Figure 29: Percent of all adult in-center hemodialysis patients dialyzed with a catheter continuously for 90 days or longer as their vascular access on their last hemodialysis session during October–December 2001, by Network. 2002 ESRD CPM Project.

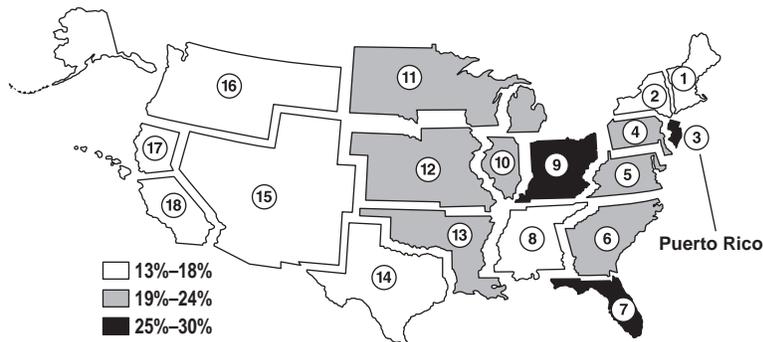


TABLE 9: Percent of all adult in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 2001, by gender, race, ethnicity, age and Network. 2002 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US
ALL	46	38	32	28	25	28	29	29	28	32	29	35	24	23	35	45	33	35	31
GENDER																			
Men	57	50	40	38	36	38	39	39	37	44	39	43	33	32	45	54	44	46	41
Women	33	25	20	16	13	19	16	19	16	20	19	25	14	13	25	33	20	24	20
RACE																			
Black	35	36	28	25	25	27	24	26	27	29	27	27	24	21	*	40	22	35	27
White	49	37	37	31	25	33	32	34	28	35	28	37	23	24	38	47	31	35	33
ETHNICITY																			
Hispanic	50	39	32	*	*	*	27	*	*	31	*	*	*	22	40	50	36	36	32
Non-Hispanic	46	38	32	29	25	28	29	30	27	32	30	34	24	24	34	45	32	34	31
AGE GROUP (years)																			
18-44	63	46	39	33	39	39	40	38	36	32	41	40	41	33	39	52	40	52	41
45-54	52	49	27	41	28	33	26	32	36	38	37	46	31	32	40	38	44	38	36
55-64	50	35	33	32	24	31	34	28	29	28	32	36	19	22	32	47	28	43	31
65-74	42	40	37	24	22	18	20	23	26	31	22	30	16	17	35	43	30	22	26
75+	38	25	24	22	14	22	29	20	17	31	23	27	16	14	32	43	29	23	24

* Value suppressed because $n \leq 10$.

TABLE 10: Percent of all adult in-center hemodialysis patients with a catheter access on their last hemodialysis session during October–December 2001, by gender, race, ethnicity, age and Network. 2002 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	25	22	36	29	28	27	32	21	33	27	27	27	27	20	25	19	17	20	26	
GENDER																				
Men	16	18	34	22	23	26	26	17	29	21	25	23	24	19	23	18	14	14	22	
Women	35	27	39	36	33	28	39	24	38	32	29	30	30	20	27	22	21	26	30	
RACE																				
Black	23	22	32	19	24	26	32	20	29	23	17	28	21	19	24	*	22	17	24	
White	25	26	35	35	36	30	33	21	36	29	31	27	34	20	26	21	19	20	28	
ETHNICITY																				
Hispanic	*	*	43	*	*	*	41	*	*	*	*	*	*	16	21	*	11	19	21	
Non-Hispanic	26	23	33	29	29	27	31	21	34	27	27	27	27	21	26	20	19	20	26	
AGE GROUP (years)																				
18-44	*	28	38	27	27	29	32	19	25	23	21	27	22	18	32	25	15	17	24	
45-54	*	*	51	*	26	22	40	25	33	25	31	20	20	16	22	24	*	18	23	
55-64	26	22	31	29	30	19	25	16	36	29	21	25	23	25	27	16	18	20	24	
65-74	21	22	30	28	27	34	28	25	33	25	27	30	31	14	19	20	16	18	25	
75+	34	28	38	36	31	29	38	20	37	31	32	28	38	26	27	14	24	27	31	

* Value suppressed because $n \leq 10$.

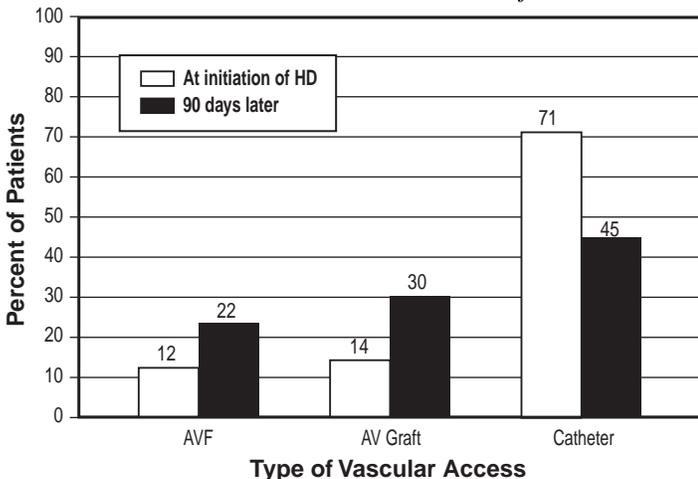
Table 11 depicts the odds ratio (95% CI) for a patient having an AVF as his/her vascular access on his/her last hemodialysis session during October-December 2001 by selected patient characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a male has an almost three times greater chance of having an AVF for his vascular access compared to a female (without controlling for any other variables).

26% (n=2121) of all patients in the sample for analysis were dialyzed with a catheter during their last hemodialysis session of the study period (TABLE 8). A higher percent of women compared to men, Whites compared to Blacks, patients aged 75 years or more compared to younger patients, and patients dialyzing less than six months compared to those patients dialyzing six months or longer were dialyzed with a catheter (TABLE 8). The most common reasons for catheter placement were: the fistula or graft was maturing, not ready to cannulate (24%), no fistula or graft surgically planned (23%) and no fistula or graft surgically created at this time (20%) (TABLE 12). 14% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

51% of patients with an AVF or AV graft (n=6187) had their vascular access monitored for stenosis during the study period. For this subset of patients, 60% were monitored with dynamic venous pressure, 13% with static venous pressure, 11% with the dilution technique, 4% with Color-flow Doppler, and 19% 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; 22% of incident patients had an AVF as their vascular access 90 days later (FIGURE 30). 71% of incident patients had a catheter as their vascular access upon initiation of a maintenance course of hemodialysis; 45% of incident patients had a catheter as their vascular access 90 days later (FIGURE 30).

Figure 30: 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, October-December 2001. 2002 ESRD CPM Project.



*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 2001 and August 31, 2001.

TABLE 11: Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for having an AV fistula access, October-December 2001. 2002 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
GENDER	
Male	2.8 (2.5, 3.1)
Female (referent)	
RACE	
White	1.4 (1.3, 1.6)
Black (referent)	
AGE GROUP (years)	
18-44	1.7 (1.5, 1.9)
45+ (referent)	
DIABETES MELLITUS	
Yes	0.74 (0.67, 0.81)
No (referent)	
QUARTILE POST-DIALYSIS BMI	
Quartile 2	1.1 (1.0, 1.3)
Quartile 3	0.99 (0.87, 1.1)
Quartile 4 (highest)	0.74 (0.65, 0.85)
(Quartile 1 = referent)	

TABLE 12: Reasons for catheter placement in adult in-center hemodialysis patients on their last hemodialysis session during October-December 2001. 2002 ESRD CPM Project.

Reason	n	(%)
TOTAL	2121	(100)
Fistula or graft maturing, not ready to cannulate	500	(24)
No fistula or graft surgically planned	478	(23)
Patient preference	267	
Peripheral vascular disease	169	
Patient size too small for AV fistula/graft	49	
Physician preference	39	
Renal transplantation scheduled	16	
No fistula or graft surgically created at this time	429	(20)
All fistula or graft sites have been exhausted	302	(14)
Temporary interruption of fistula or graft use due to clotting, revision, or other reasons	276	(13)
Other	120	(6)

*Note: Subtotals may not add up to 2121 as respondents could choose multiple reasons. Percents may not add up to 100% due to rounding.

3. CPM and Other Findings for October-December 2001 compared to previous study periods.

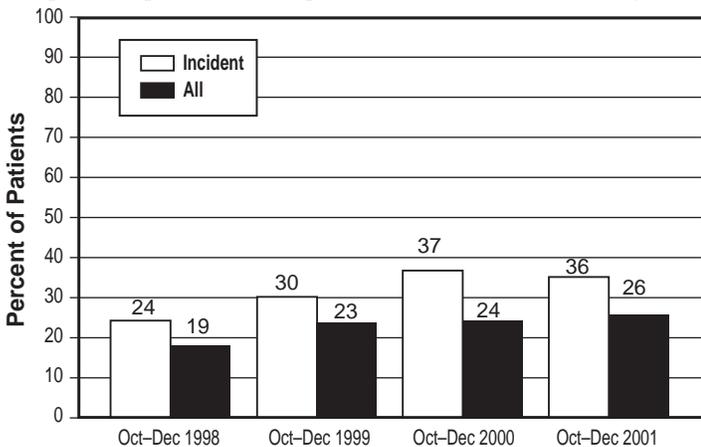
More patients were dialyzed with a catheter on their last hemodialysis session during October-December 2001 compared to October-December 1998, 1999 and 2000 (26% compared to 19%, 23% and 24%, respectively) (FIGURES 4, 31). A similar pattern was noted for incident patients, with 36% of incident patients in late 2001 dialyzed with a catheter on their last hemodialysis session compared to 24% in late 1998, 30% in late 1999, and 37% in late 2000 (FIGURE 31).

There was some change in the percent of all patients dialyzed with an AVF on their last hemodialysis session from late 1998 to late 2001 (26% vs. 31%, respectively) (FIGURE 32). 26% of incident patients were dialyzed with an AVF on their last hemodialysis session in late 1998 compared to 29% in late 2001 (FIGURE 32).

14% of all patients were dialyzed with a chronic catheter continuously for 90 days or longer during late 1998 and 1999, compared to 19% of all patients during October-December 2001 (FIGURE 4).

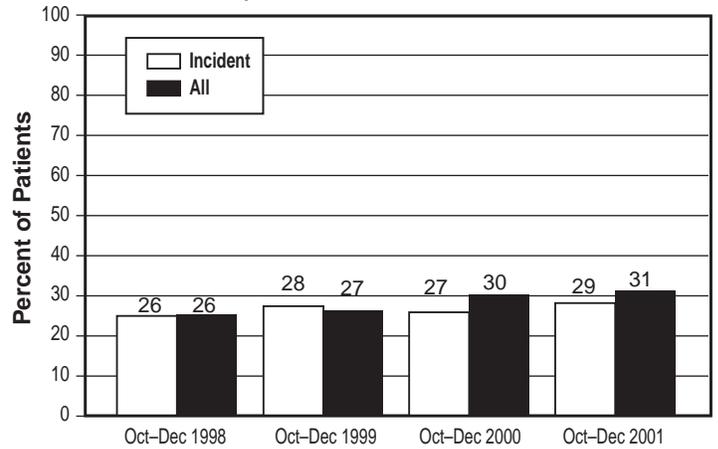
There has been little change in the percent of different types of stenosis monitoring for patients with either an AVF or an AV graft as their vascular access from late 2000 to late 2001 (FIGURE 33).

Figure 31: 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 2001 compared to previous study periods. 2002 ESRD CPM Project.



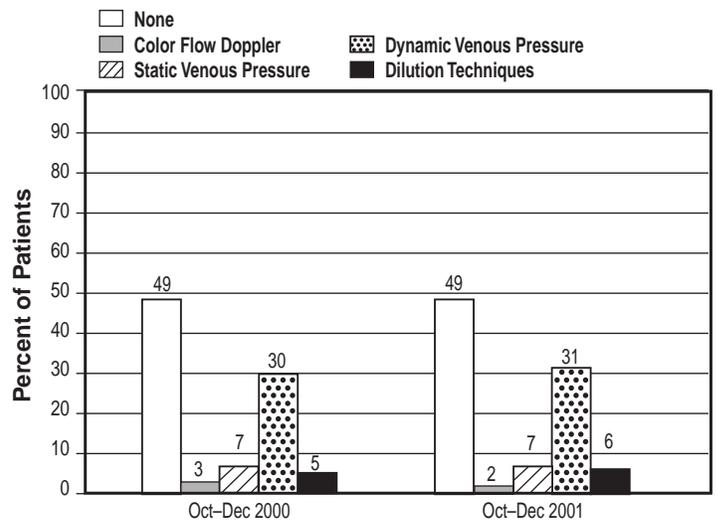
*An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1 and August 31, of the study year.

Figure 32: 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 2001 compared to previous study periods. 2002 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 33: 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 2001 compared to October-December 2000. 2002 ESRD CPM Project.



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

C. ANEMIA MANAGEMENT

1. CPM and Other Findings for October–December 2001

Data to assess three anemia management CPMs were collected in 2002. The time period from which these data were abstracted was October–December 2001.

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

FINDING: For the last quarter of 2001, 38% of the in-center hemodialysis patients who met the inclusion criteria (n=8200) had a mean hemoglobin 11–12.0 gm/dL.

Anemia Management CPM Ila — For all anemic patients (hemoglobin < 11 gm/dL) 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 2001, 92% of the in-center hemodialysis patients who met the inclusion criteria (n=8165) 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 gm/dL) or patients prescribed Epoetin, at least one serum ferritin concentration ≥ 100 ng/mL and at least one transferrin saturation $\geq 20\%$ were documented during the three-month study period.

FINDING: For the last quarter of 2001, 75% of the in-center hemodialysis patients who met the inclusion criteria (n=8165) had at least one documented transferrin saturation $\geq 20\%$ and at least one documented serum ferritin concentration ≥ 100 ng/mL during the study period.

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

FINDING: 77% of the in-center hemodialysis patients who met the inclusion criteria (n=2600) were prescribed intravenous iron in at least one month during October–December 2001.

2. Other Anemia Management Findings for October–December 2001

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 34 for both Black and White patients. The mean (\pm SD) hemoglobin value for all patients in this sample was 11.7 gm/dL (± 1.2 gm/dL). The mean hemoglobin values for gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters are shown in Table 13.

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

The mean hemoglobin value was higher for patients with a mean Kt/V ≥ 1.2 compared to patients with a mean Kt/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 13).

Figure 34: Distribution of mean hemoglobin values for adult in-center hemodialysis patients in the US, by race, October–December 2001. 2002 ESRD CPM Project.

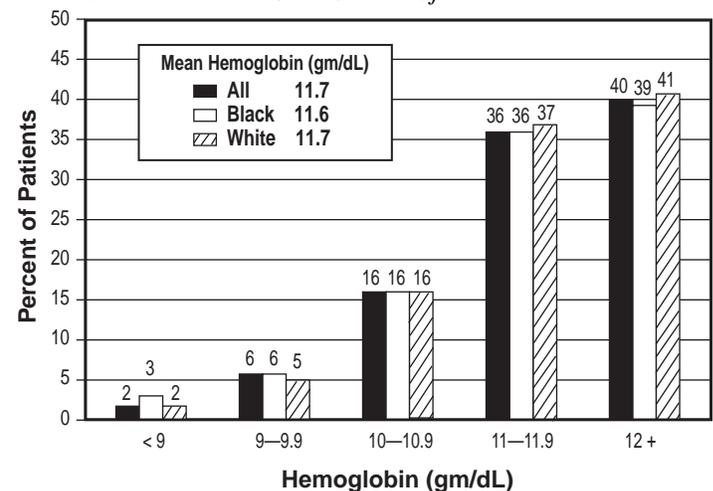


TABLE 13: Mean hemoglobin values (gm/dL) for adult in-center hemodialysis patients in the US, by patient characteristics, October–December 2001. 2002 ESRD CPM Project.

Patient Characteristic	Mean hemoglobin (gm/dL)	Percent of patients with hemoglobin values				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.7	2	6	16	36	40
GENDER						
Men	11.7	2	6	14	35	42
Women	11.6	2	6	18	37	37
RACE						
American Indian/ Alaska Native	11.8	*	*	14	41	39
Asian/Pacific Islander	11.7	*	4	18	35	41
Black	11.6	3	6	16	36	39
White	11.7	2	5	16	37	41
Other/Unknown	11.6	4	7	18	31	39
ETHNICITY						
Hispanic	11.7	2	5	16	37	40
Non-Hispanic	11.7	2	6	16	36	40
AGE GROUP (years)						
18-44	11.7	4	6	16	33	42
45-54	11.7	3	6	15	36	40
55-64	11.7	3	6	15	36	41
65-74	11.6	2	6	18	37	38
75+	11.7	1	4	16	38	40
DIAGNOSIS						
Diabetes mellitus	11.7	2	6	17	37	39
Hypertension	11.7	3	6	16	35	41
Glomerulonephritis	11.7	2	6	16	37	40
Other/Unknown	11.7	3	5	14	36	42
DURATION of DIALYSIS (years)						
< 0.5	11.2	7	13	23	24	32
0.5-0.9	11.9	1	4	15	32	48
1.0-1.9	11.8	1	4	14	39	42
2.0+	11.7	2	5	15	39	39
MEAN Kt/V						
≥ 1.2	11.7	2	5	16	37	41
< 1.2	11.4	6	10	17	31	36
MEAN SERUM ALBUMIN (gm/dL)						
≥ 3.5/3.2 BCG/BCP [^]	11.8	1	4	14	37	43
< 3.5/3.2 BCG/BCP	11.1	8	13	22	31	26
ACCESS TYPE						
AVF	11.8	1	4	13	37	45
AV Graft	11.7	2	5	15	39	40
Catheter	11.4	5	9	20	31	35

* Value suppressed because n ≤ 10.

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

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

The percent of patients with mean hemoglobin < 9 gm/dL was 2%. The percent of patients with mean hemoglobin < 10 gm/dL was 8%. The prevalence of patients with mean hemoglobin < 10 gm/dL 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, and, as reported previously, higher in Blacks than in Whites (30).

A higher proportion of patients with a mean Kt/V < 1.2 compared to patients with higher mean Kt/V values had a mean hemoglobin value < 10 gm/dL. A higher proportion of patients dialyzed with a catheter had a mean hemoglobin < 10 gm/dL 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 gm/dL (BCG/BCP) compared to patients with higher mean serum albumin values had a mean hemoglobin < 10 gm/dL (TABLE 13). The prevalence of patients with mean hemoglobin < 10 gm/dL ranged from 5% to 11% among Networks (FIGURE 35).

Figure 35: Percent of adult in-center hemodialysis patients with mean hemoglobin < 10 gm/dL, by Network, October–December 2001. 2002 ESRD CPM Project.

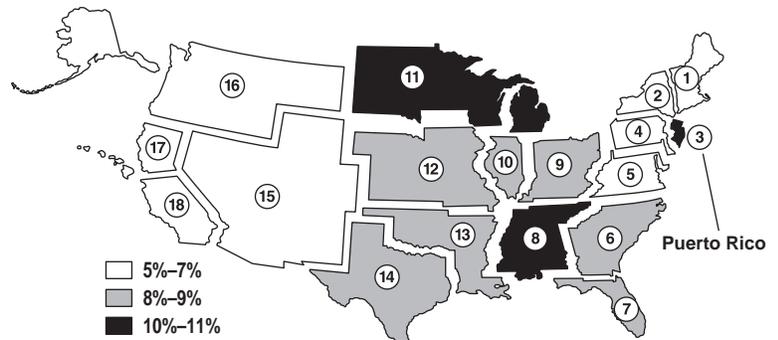


Table 14 shows, by Network, gender, race, ethnicity, and age group, the percent of patients with hemoglobin values ≥ 11 gm/dL. The percent of all patients with mean hemoglobin ≥ 11 gm/dL was 76% nationally and ranged from 73% to 81% by Network (TABLE 14) (FIGURES 36, 37). The percent of all patients with mean hemoglobin ≥ 11 gm/dL by race and age group is shown in Figure 38.

The percent of patients with mean hemoglobin ≥ 11 gm/dL by selected patient characteristics and clinical parameters is shown in Figure 39. More patients dialyzing for six months or longer had a mean hemoglobin ≥ 11 gm/dL compared to patients dialyzing less than six months (79% vs. 56%, respectively). A higher percent of patients dialyzed with an AVF or an AV graft met this threshold compared to patients dialyzed with a catheter (81% and 79% compared to 66%, respectively). Patients with higher mean Kt/V and serum albumin values were more likely to meet this hemoglobin target than patients with lower Kt/Vs and serum albumin values.

TABLE 14: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by gender, race, ethnicity, age and Network, October-December 2001. 2002 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	75	78	77	77	76	78	73	74	76	76	75	73	76	81	78	76	77	76
GENDER																			
Men	78	77	79	80	77	77	80	78	75	76	76	78	76	80	81	79	76	78	78
Women	72	73	77	73	77	75	76	69	72	76	76	72	70	71	80	77	76	76	74
RACE																			
Black	71	71	83	76	76	74	77	73	71	73	73	71	74	84	73	79	71	77	75
White	76	78	76	77	80	78	79	73	75	78	78	79	73	73	82	78	78	79	77
ETHNICITY																			
Hispanic	77	73	73	*	79	*	75	*	*	84	*	*	69	75	83	86	76	77	77
Non-Hispanic	76	76	80	77	77	75	79	73	73	75	76	74	73	76	80	78	76	77	76
AGE GROUP (years)																			
18-44	79	82	70	77	67	74	77	70	73	73	72	67	73	77	82	77	73	77	74
45-54	74	75	71	77	72	80	68	78	82	73	72	79	74	78	78	72	83	82	77
55-64	66	72	83	72	82	82	74	73	64	77	86	76	74	81	77	79	76	80	77
65-74	79	71	77	76	80	67	84	68	70	79	76	70	73	73	80	77	76	70	74
75+	79	79	82	82	83	76	82	77	80	75	75	82	72	70	87	83	75	78	79

*Value suppressed because $n \leq 10$.

Figure 36: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by Network, October–December 2001. 2002 ESRD CPM Project.

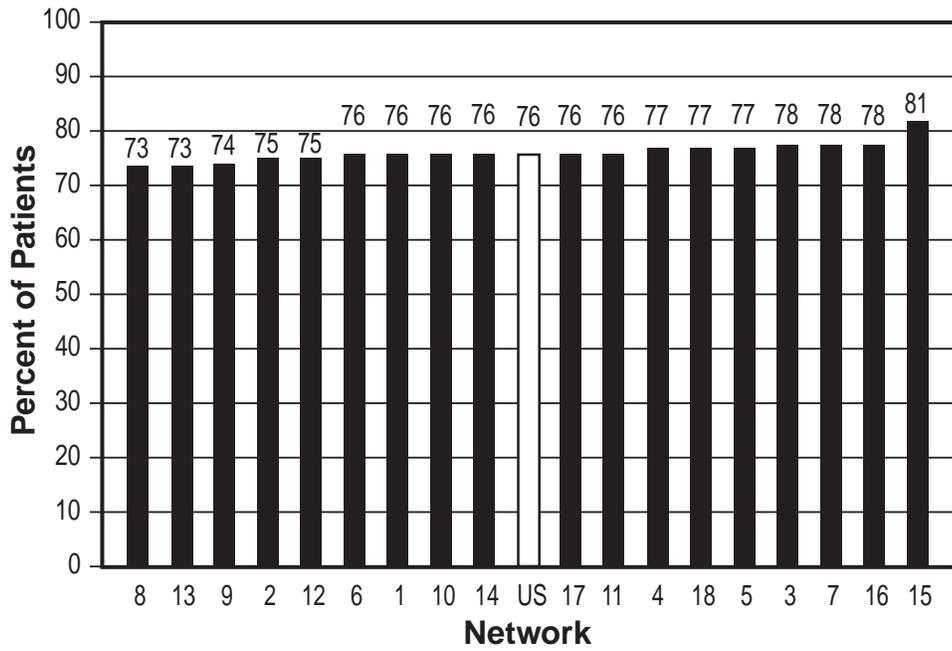


Figure 37: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by Network, October–December 2001. 2002 ESRD CPM Project.

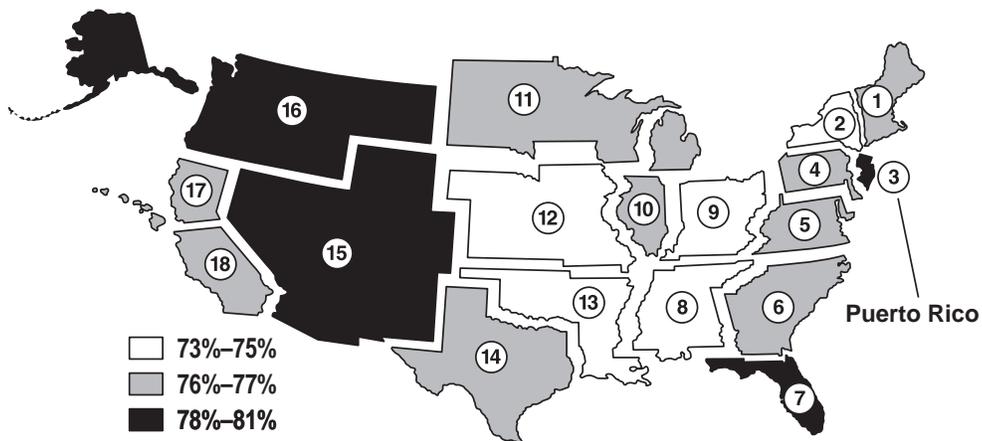


Figure 38: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by age and race, October–December 2001. 2002 ESRD CPM Project.

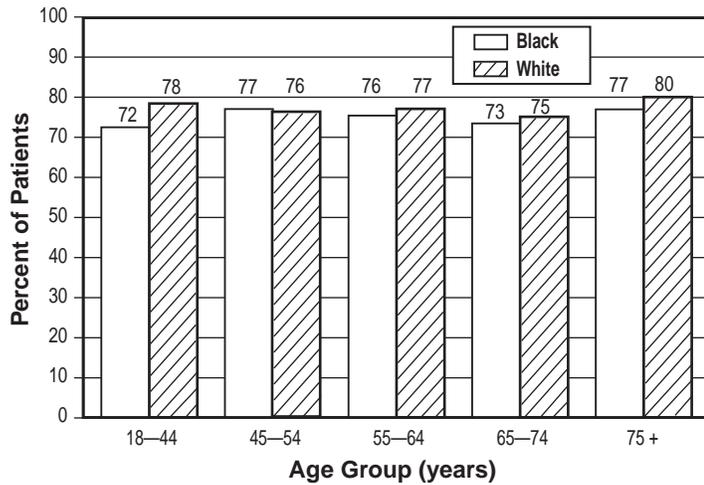
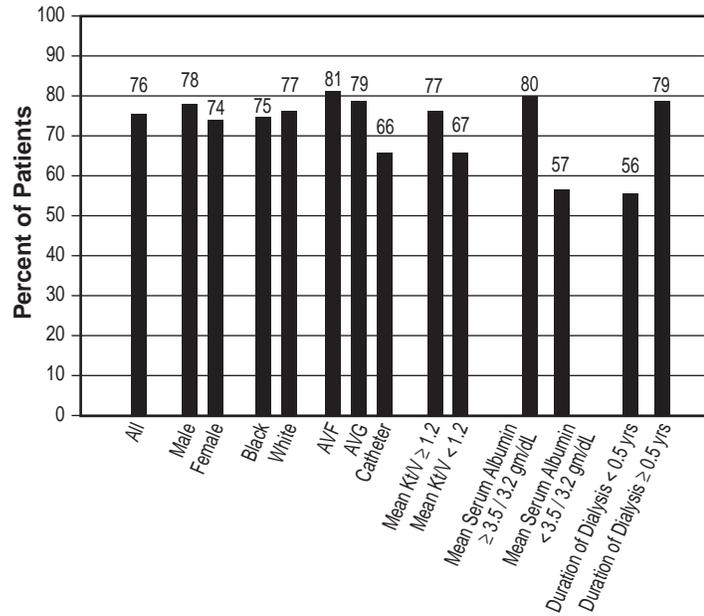


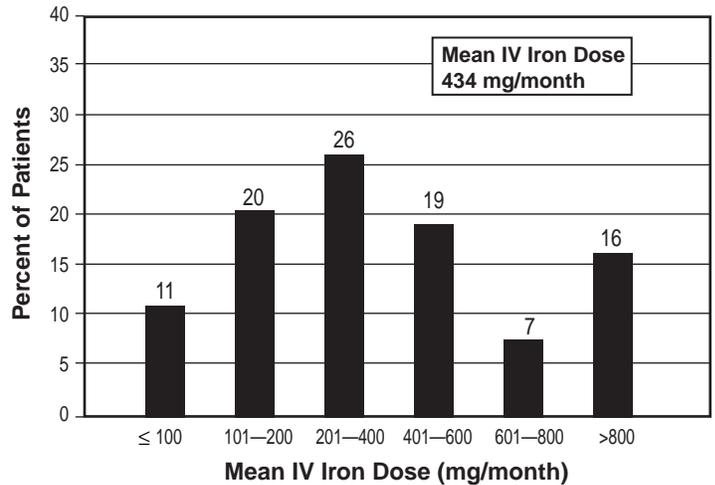
Figure 39: Percent of adult in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by selected patient characteristics and clinical parameters, October–December 2001. 2002 ESRD CPM Project.



During this study period, data were collected on additional measures related to anemia management (TABLE 15).

The national average (\pm SD) transferrin saturation for the patients in the sample was 29.3% (\pm 12.5%) and ranged from 26.7% to 31.3% among the 18 Network areas (TABLE 15). Table 15 also provides the percent of patients with mean transferrin saturation $\geq 20\%$ nationally (80%) and by Network area, ranging from 70% to 86%.

Figure 40: Distribution of mean intravenous iron doses (mg/month) for adult in-center hemodialysis patients, October–December 2001. 2002 ESRD CPM Project.



The national average (\pm SD) serum ferritin concentration for the patients in the sample was 600 ng/mL (\pm 422 ng/mL) and ranged from 500 to 725 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 87% to 95% among the 18 Network areas (TABLE 15).

67% 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 59% to 70% among the 18 Network areas (TABLE 15).

For the subset of patients with both mean transferrin saturation $< 20\%$ and mean serum ferritin concentration < 100 ng/mL ($n=292$ or 4% of patients), only 70% were prescribed IV iron at least once during the three-month study period.

The mean administered IV iron dose was 434 mg/month (\pm 333 mg/month). The distribution of mean administered IV iron doses (mg/month) is shown in Figure 40.

96% of patients were prescribed Epoetin, of which 91% were prescribed Epoetin by the IV route; and 10% 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 3% to 19% among the 18 Network areas (TABLE 15). The mean (\pm SD) weekly Epoetin dose for patients prescribed Epoetin by the IV route was 256.4 units/kg/week (\pm 232.9 units/kg/week); by the SC route was 216.7 units/kg/week (\pm 204.6 units/kg/week).

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

TABLE 15: Regional variation for various anemia management measures for adult in-center hemodialysis patients including the percent of patients with mean hemoglobin ≥ 11 gm/dL, mean hemoglobin (gm/dL), and mean serum albumin ≥ 4.0 gm/dL[^], for these patients nationally and by Network, October-December 2001. 2002 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 gm/dL	76	75	78	77	77	76	78	73	74	76	76	75	73	76	81	78	76	77	76
Mean hemoglobin (gm/dL)	11.6	11.7	11.7	11.6	11.7	11.7	11.7	11.5	11.7	11.8	11.6	11.6	11.6	11.7	11.9	11.9	11.7	11.6	11.7
Percent of patients with mean serum albumin ≥ 4.0 gm/dL [^]	30	38	33	34	40	36	33	34	31	33	34	29	35	37	33	29	34	42	35
Average transferrin saturation (TSAT) (%)	27.7	31.1	29.3	29.4	30.3	31.3	31.2	28.8	28.4	28.5	29.9	26.9	28.5	28.1	27.2	26.7	27.9	30.2	29.3
Percent of patients with mean TSAT $\geq 20\%$	78	81	82	79	83	85	86	78	77	79	79	74	79	79	77	70	75	85	80
Average serum ferritin concentration (ng/mL)	500	580	564	571	559	624	725	601	630	677	606	557	652	584	538	527	570	631	600
Percent of patients with mean serum ferritin concentration ≥ 100 ng/mL	89	87	91	90	90	92	94	93	95	93	93	91	92	92	90	89	90	93	92
Percent of patients with IV iron prescribed	62	63	64	65	59	60	65	61	70	68	68	62	60	65	63	69	62	60	64
Percent of patients * with subcutaneous Epoetin prescribed	7	4	12	3	4	3	4	5	19	13	11	18	9	15	*	14	15	19	10
Percent of patients with mean hemoglobin < 11 gm/dL with Epoetin prescribed	100	94	99	98	95	100	98	95	99	98	96	95	96	95	97	97	96	96	97

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

*Among patients prescribed Epoetin

Table 16 depicts the odds ratio (95% CI) for experiencing a mean hemoglobin < 11 gm/dL by several patient and clinical characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a female had a 1.2 (or 20%) greater chance of experiencing a mean hemoglobin < 11 gm/dL than a male (without controlling for any other variables).

TABLE 16: Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for mean hemoglobin < 11 gm/dL. 2002 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
GENDER	
Female	1.2 (1.1, 1.4)
Male (referent)	
RACE	
Black	1.2 (1.0, 1.3)
White (referent)	
ETHNICITY	
Hispanic	0.93 (0.79, 1.1)
Non-Hispanic (referent)	
AGE GROUP (years)	
18-44	1.1 (0.99, 1.3)
45+ (referent)	
DIABETES MELLITUS	
Yes	1.1 (0.95, 1.2)
No (referent)	
DURATION OF DIALYSIS (years)	
< 0.5	2.8 (2.5, 3.2)
≥ 0.5 years (referent)	
MEAN Kt/V	
< 1.2	1.7 (1.5, 1.9)
≥ 1.2 (referent)	
MEAN SERUM ALBUMIN (gm/dL)	
< 3.5/ < 3.2 (BCG/BCP)*	3.0 (2.7, 3.4)
≥ 3.5/ ≥ 3.2 (BCG/BCP) (referent)	
EPOETIN	
prescribed during study period not prescribed (referent)	1.4 (1.1, 1.9)
MEAN TRANSFERRIN SATURATION	
< 20%	2.6 (2.3, 3.0)
≥ 20% (referent)	
MEAN SERUM FERRITIN CONCENTRATION (ng/mL)	
< 100	1.6 (1.3, 1.9)
≥ 100 (referent)	
VASCULAR ACCESS	
AV Graft	1.2 (1.0, 1.3)
Catheter (AVF = referent)	2.3 (2.0, 2.6)

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

3. CPM and Other Findings for October-December 2001 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 average hemoglobin (\pm SD) from October–December 2000 to October–December 2001 increased from 11.6 gm/dL (\pm 1.2) to 11.7 gm/dL (\pm 1.2) (FIGURE 9), and the percent of patients with a mean hemoglobin \geq 11 gm/dL increased significantly from 74% to 76% (FIGURES 8, 9, 41).

In addition to the improvement in the percent of patients with mean hemoglobin \geq 11 gm/dL, there was also a decrease in the percent of patients with mean hemoglobin < 10 gm/dL. In October–December 2000, 10% of Black patients and 8% of White patients had a mean hemoglobin < 10 gm/dL, while in October–December 2001, 9% of Black patients and 7% of White patients had a mean hemoglobin < 10 gm/dL.

The percent of patients prescribed Epoetin by hemoglobin category in late 1997, 1998, 1999, 2000 and 2001 is shown in Figure 42. Figure 43 depicts the trend for increasing weekly Epoetin dosing (units/kg/week) for selected years from late 1997 to late 2001. SC Epoetin doses were systematically lower than IV Epoetin doses at all hemoglobin categories examined. Of the patients prescribed Epoetin, 10% of patients were prescribed SC Epoetin in late 2001, a slight change from late 2000. (FIGURE 44)

Figure 44 also depicts the status of iron stores for the sampled patients in late 2001 compared to selected previous study periods. Overall, 64% of patients were prescribed IV iron in late 2001 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 70% of patients were prescribed IV iron at least once over the three-month study period in late 2001, compared to 37% in late 1996.

Figure 41: Percent of adult in-center hemodialysis patients with mean hemoglobin values ≥ 11 gm/dL, by race, October–December 2001 compared to previous study periods. 2002 ESRD CPM Project.

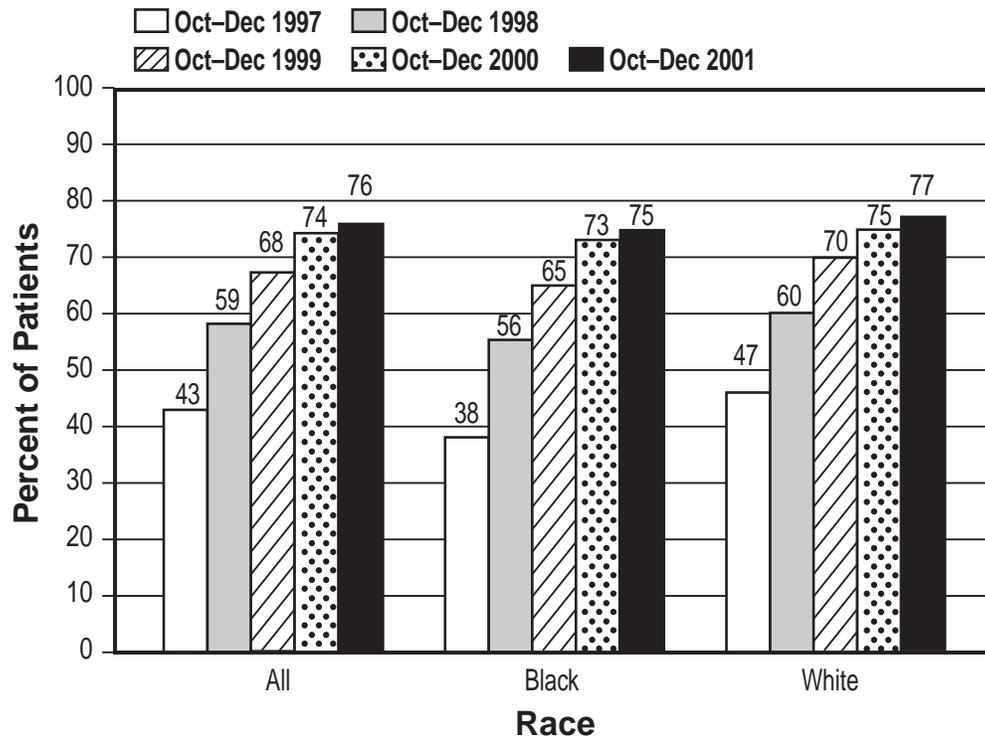


Figure 42: Percent of adult in-center hemodialysis patients who were prescribed Epoetin by hemoglobin category, October–December 2001 compared to previous study periods. 2002 ESRD CPM Project.

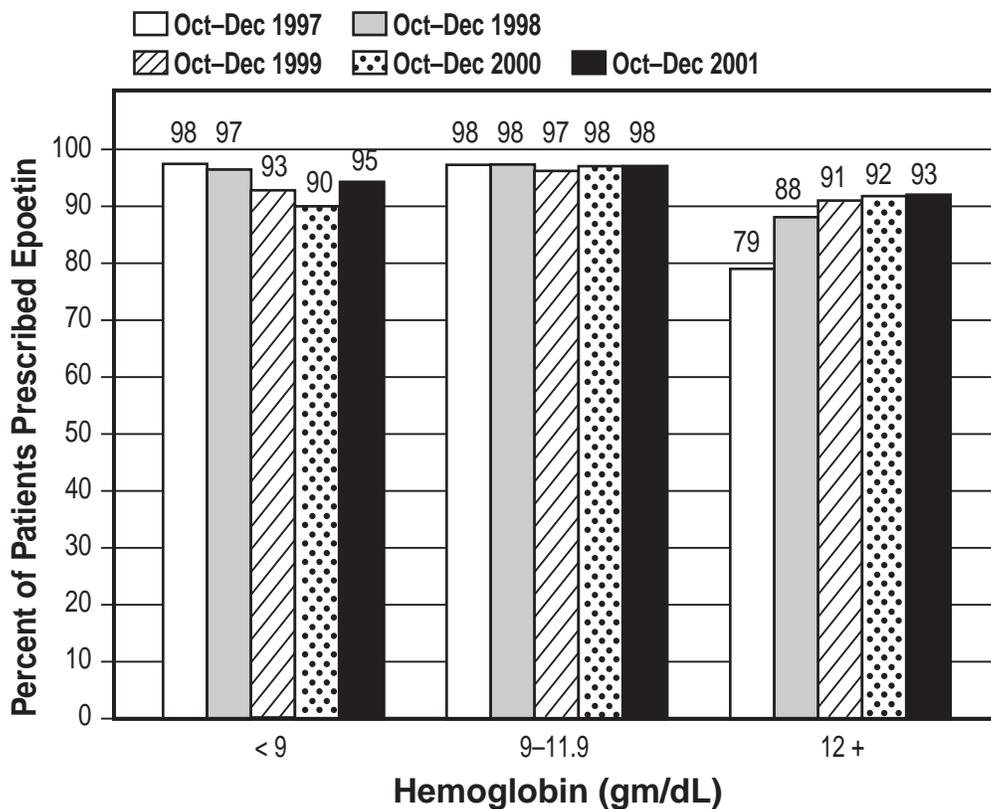


Figure 43: Mean prescribed weekly Epoetin dose (units/kg/week) for adult in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 2001 compared to selected previous study periods. 2002 ESRD CPM Project.

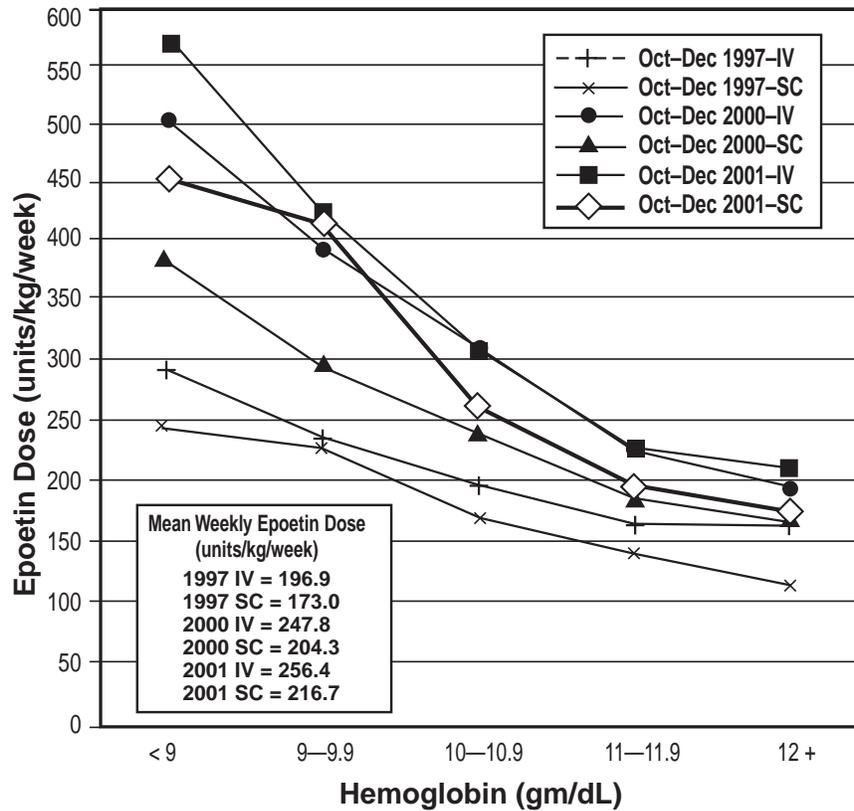
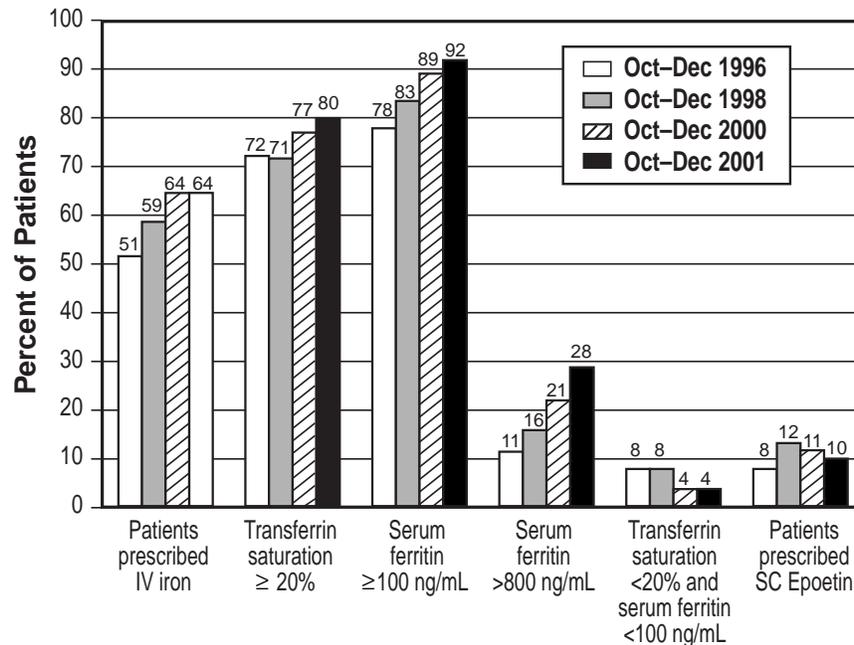


Figure 44: Percent of adult in-center hemodialysis patients with specific anemia management indicators, October–December 2001 compared to selected previous study periods. 2002 ESRD CPM Project.



D. SERUM ALBUMIN

1. Findings for October–December 2001

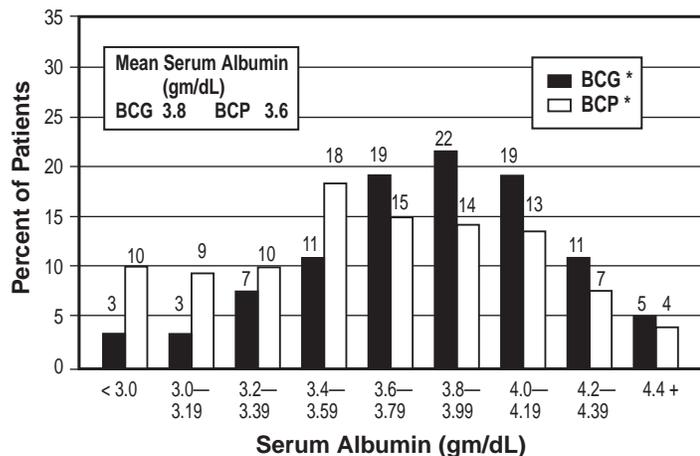
The two commonly used laboratory methods for determining serum albumin values, bromcresol green (BCG) and bromcresol purple (BCP), have been reported to yield systematically different results (24). Therefore, we assessed the serum albumin values reported for these two methods separately. As expected, the values determined by the BCP method were systematically lower than those determined by the BCG method.

The mean (± SD) serum albumin value for patients whose value was determined by the BCG method (n=7478) was 3.8 gm/dL (± 0.4 gm/dL), and by the BCP method (n=895) was 3.6 gm/dL (± 0.5 gm/dL).

Mean serum albumin < 3.5 gm/dL by the BCG method has been shown to be a marker for diminished survival (31-33). Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we also defined a mean BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. “Optimal” serum albumin was defined as ≥ 4.0 gm/dL by the BCG method or ≥ 3.7 gm/dL by the BCP method. Figure 45 displays the distribution of serum albumin values by laboratory method.

The percents of patients with mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) and ≥ 3.5/3.2 gm/dL (BCG/BCP) by gender, race, ethnicity, age, diagnosis groups, duration of dialysis, and selected clinical parameters are shown in Table 17. 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 ≥ 4.0/3.7 gm/dL (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 (TABLE 17).

Figure 45: Distribution of mean serum albumin for adult in-center hemodialysis patients, by laboratory method, October–December 2001. 2002 ESRD CPM Project.



* Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

A higher percent of patients with a mean hemoglobin ≥ 11 gm/dL had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) compared to patients with lower mean hemoglobin values (40% vs. 24%, respectively). More patients dialyzed with either an AVF or an AV graft compared to patients dialyzed with a catheter had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) (45% and 37% vs. 24% respectively) (TABLE 17).

TABLE 17: Percent of adult in-center hemodialysis patients with mean serum albumin values ≥ 4.0/3.7 gm/dL (BCG/BCP)* and ≥ 3.5/3.2 gm/dL (BCG/BCP) in the US, by patient characteristics, October-December 2001. 2002 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin ≥ 4.0/3.7 gm/dL	Percent of Patients with Mean Serum Albumin ≥ 3.5/3.2 gm/dL
TOTAL	36	82
GENDER		
Men	42	85
Women	29	79
RACE		
American Indian/ Alaska Native	33	79
Asian/Pacific Islander	39	86
Black	40	84
White	33	80
Other/Unknown	35	77
ETHNICITY		
Hispanic	41	83
Non-Hispanic	35	82
AGE GROUP (years)		
18-44	50	88
45-54	42	82
55-64	37	82
65-74	30	80
75+	25	78
DIAGNOSIS		
Diabetes mellitus	30	78
Hypertension	41	86
Glomerulonephritis	45	87
Other/Unknown	37	82
DURATION of DIALYSIS (years)		
< 0.5	17	61
0.5-0.9	29	80
1.0-1.9	36	83
2.0+	42	86
MEAN Kt/V		
≥ 1.2	37	83
< 1.2	28	72
MEAN Hgb (gm/dL)		
≥ 11	40	86
< 11	24	68
ACCESS TYPE		
AVF	45	88
AF Graft	37	85
Catheter	24	70

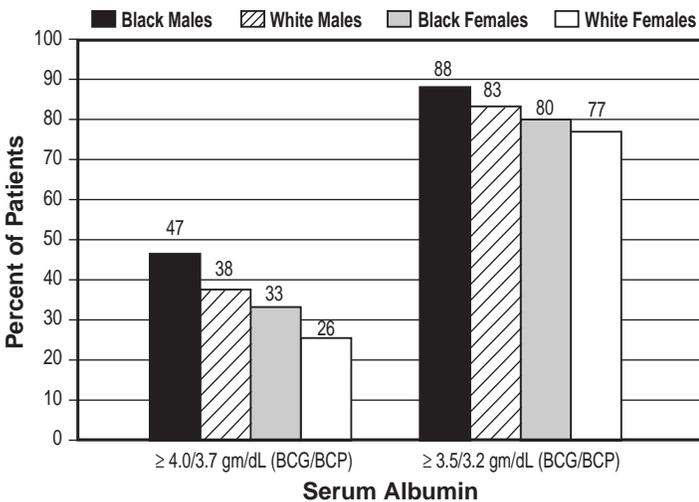
* Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

Nationally, 36% of patients had mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) ranging from 27% to 43% among the 18 Networks; 82% of patients had mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP) ranging from 73% to 86% among the 18 Networks. The percent of patients in each Network area, by gender, race, ethnicity, and age group, with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) is shown in Table 18.

The percent of patients achieving on average either an “adequate” or an “optimal” serum albumin over the three month study period tended to be higher for men compared to women, for Black patients compared to White patients, and for patients 18-44 years old compared to older patients (FIGURE 46, TABLES 17 and 18).

A higher percentage of patients with causes of ESRD other than diabetes mellitus achieved on average an “optimal” serum albumin over the three month study period compared to patients with diabetes mellitus as the cause of ESRD (41% vs. 30% respectively). Only 17% of patients dialyzing less than six months achieved an “optimal” serum albumin compared to 42% of patients dialyzing two or more years.

Figure 46: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP), by race and gender, October–December 2001. 2002 ESRD CPM Project.



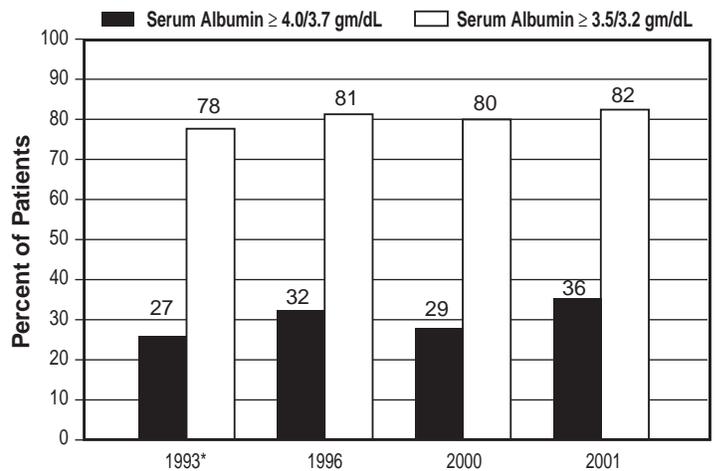
*Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

2. Findings for October–December 2001 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 2001 compared to previous study periods.

Figure 47 shows the percent of patients with mean serum albumin ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP) and the percent of patients with mean serum albumin values ≥ 3.5 gm/dL (BCG) or ≥ 3.2 gm/dL (BCP) during October–December 2001 compared to selected previous study periods.

Figure 47: Percent of adult in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)** and $\geq 3.5/3.2$ gm/dL (BCG/BCP), October–December 2001 compared to selected previous study periods. 2002 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 = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

TABLE 18: Percent of adult in-center hemodialysis patients with mean serum albumin ≥ 4.0 gm/dL (BCG method)** or ≥ 3.7 gm/dL (BCP method)**, by gender, race, ethnicity, age and Network, October-December 2001. 2002 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	32	37	33	34	42	38	35	36	31	36	34	31	38	39	33	27	35	43	36	
GENDER																				
Men	35	43	37	41	46	45	41	44	39	42	36	39	46	48	39	32	41	46	42	
Women	28	30	27	26	37	29	28	29	22	30	32	22	29	30	27	20	28	39	29	
RACE																				
Black	31	46	36	41	44	40	35	40	31	40	42	36	42	41	29	19	30	56	40	
White	31	27	30	30	37	32	35	27	32	34	30	28	32	39	34	29	35	40	33	
ETHNICITY																				
Hispanic	*	42	34	*	*	*	33	*	*	37	*	*	*	40	40	47	34	45	41	
Non-Hispanic	31	37	33	33	41	37	35	35	31	36	34	30	38	38	32	26	36	41	35	
AGE GROUP (years)																				
18-44	47	49	38	52	52	51	46	52	53	46	44	45	54	51	41	47	46	61	50	
45-54	34	59	35	50	43	43	34	44	25	46	36	45	39	46	44	29	36	46	42	
55-64	36	32	40	37	43	38	40	34	30	36	47	33	32	39	28	22	36	53	37	
65-74	29	31	31	27	43	28	33	25	29	28	27	23	38	35	27	20	33	32	30	
75+	24	25	25	24	28	27	27	22	25	28	23	21	26	26	31	22	26	24	25	

* Value suppressed because $n \leq 10$.
 ** Note: BCG = bromocresol green laboratory method
 BCP = bromocresol purple laboratory method

ADULT PERITONEAL DIALYSIS PATIENTS OCTOBER 2001-MARCH 2002

SYNOPSIS

• Purpose of Project: The ultimate purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in improving the care provided to ESRD patients. The specific purposes of the 2002 project were:

To compare the prevalence of important clinical characteristics of adult (aged ≥ 18 years) peritoneal dialysis patients in the US in October 2001-March 2002 to the prevalence of those characteristics in November 1994-April 1995; November 1995-April 1996; November 1996-April 1997; November 1997-April 1998; October 1998-March 1999; October 1999-March 2000; and October 2000-March 2001.

AND, to identify opportunities to improve care for those patients.

• Method Used: A national random sample of adult peritoneal dialysis patients who were alive on December 31, 2001, was selected (sample size 1,451).

ESRD facilities with one or more patients in the sample submitted completed data collection forms to their respective ESRD Network. The Networks then submitted a data file to ESRD Network 9/10 with the clinical information about these patients for the time period October 2001–March 2002 for aggregation. This aggregated data file was then forwarded to CMS for initial analysis.

• Initial Findings: The sample for analysis consisted of 1,352 patients, which was 93% of the original sample. Highlights from the initial findings are summarized below.

IMPROVEMENT OCCURRED

• Adequacy of dialysis was assessed at least once for 86% of the sampled patients during the 2002 study period (October 2001–March 2002), compared to 85% of the sampled patients during the 2001 study period (October 2000-March 2001), 83% during the 2000 study period (October 1999–March 2000) and 82% during the 1999 study period (November 1998-April 1999) (FIGURE 7).

• 72% of CAPD patients had a mean weekly Kt/V_{urea} meeting NKF/DOQI guidelines (13) during the 2002 study period

compared to 67% during the 2001 study period. 66% of CAPD patients had a mean weekly creatinine clearance (CrCl) meeting these guidelines during the 2002 study period, compared to 61% during the 2001 study period (October 2000-March 2001).

• 66% of cycler patients with a daytime dwell had a mean weekly Kt/V_{urea} and 55% had a mean weekly CrCl that met NKF-DOQI guidelines (13) during the 2002 study period. This compares to 64% and 55% during the 2001 study period, respectively (TABLE 20).

• From the 2001 study period (73%) to the 2002 study period (76%) an improvement of 3 percentage points occurred in the percent of peritoneal dialysis patients with mean hemoglobin ≥ 11 gm/dL (FIGURE 10).

OPPORTUNITIES TO IMPROVE

• The adequacy of dialysis was not assessed during the 2002 study period for 14% of the sampled peritoneal dialysis patients.

• 28% of CAPD patients did not achieve an adequate weekly Kt/V_{urea} and 34% did not achieve an adequate weekly CrCl. Likewise, 34% of cycler patients with a daytime dwell did not achieve an adequate weekly Kt/V_{urea} and 45% did not achieve an adequate weekly CrCl.

• 24% of patients did not have a mean hemoglobin ≥ 11 gm/dL in the 2002 study period.

• 64% of peritoneal dialysis patients who met the inclusion criteria and were prescribed Epoetin did not have a mean hemoglobin 11–12.0 gm/dL in the 2002 study period.

• 81% of peritoneal dialysis patients did not have mean serum albumin ≥ 4.0 gm/dL (BCG method) or ≥ 3.7 gm/dL (BCP method) in the 2002 study period.

• 39% of peritoneal dialysis patients did not have mean serum albumin ≥ 3.5 gm/dL (BCG method) or ≥ 3.2 gm/dL (BCP method) in the 2002 study period.

NEXT STEPS:

Network and CMS staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2003, 2004 and beyond.

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

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 2001–March 2002 (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 2001–March 2002 and previous study periods.

A national random sample of adult (≥ 18 years) peritoneal dialysis patients who were alive on December 31, 2001, was selected (sample size=1451). 1352 patients (93%) were included in the sample for analysis.

A. ADEQUACY OF PERITONEAL DIALYSIS

1. CPM Findings for October 2001–March 2002

Data to assess three peritoneal dialysis adequacy CPMs were collected in 2002. The time period from which these data were abstracted was October 2001–March 2002. 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: 86% of adult peritoneal dialysis patients had both a weekly Kt/V_{urea} and a weekly creatinine clearance measurement reported at least once during the six-month study period.

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: 62% 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: 68% 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: 67% (228/341) of CAPD patients with a PET result within 12 months of or during the study period met the revised 2000 NKF-K/DOQI thresholds for peritoneal dialysis adequacy (34) (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/week/1.73m², OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period).

FINDING: 70% 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: 61% 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 2001-March 2002

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 1,129 (85%) of the 1,322 patients included for these analyses during the 2002 study period.

Table 19 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. There has not been much change in the percent of CAPD patients meeting NKF-K/DOQI adequacy thresholds over the past two study periods. Figures 5 and 6 depict the delivered adequacy of dialysis for CAPD patients from the 1995-2002 study periods.

66% of cycler patients with a daytime dwell had a mean calculated weekly Kt/V_{urea} and 55% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2002 study period (TABLE 20). 61% of cycler patients without a daytime dwell had a mean calculated weekly Kt/V_{urea} and 53% had a mean calculated weekly creatinine clearance that met recommended NKF-K/DOQI guidelines during the 2002 study period. Figures 48 and 49 depict the delivered adequacy of dialysis for cycler patients with a daytime dwell (CCPD patients) from the 1996-2002 study periods.

45% of patients (n=591) had one or more Peritoneal Equilibration Test (PET) results within 12 months of or during the study period. The distribution of PET results is depicted in Figure 50.

32% of CAPD patients had a total prescription volume of 8000 mL and 33% had a total prescription volume of 10,000 mL (FIGURE 51).

Figure 48: Distribution of mean weekly Kt/V_{urea} for adult cycler patients with a daytime dwell, October 2001–March 2002 compared to previous study periods. 2002 ESRD CPM Project.

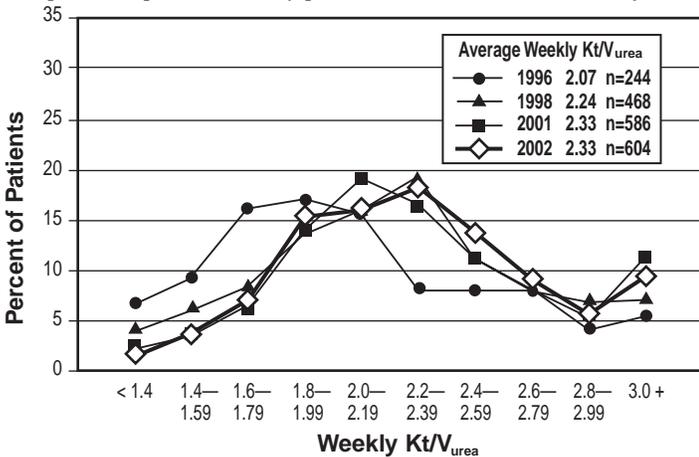


Figure 49: Distribution of mean weekly creatinine clearance (L/week/1.73m²) for adult cycler patients with a daytime dwell, October 2001–March 2002 compared to previous study periods. 2002 ESRD CPM Project.

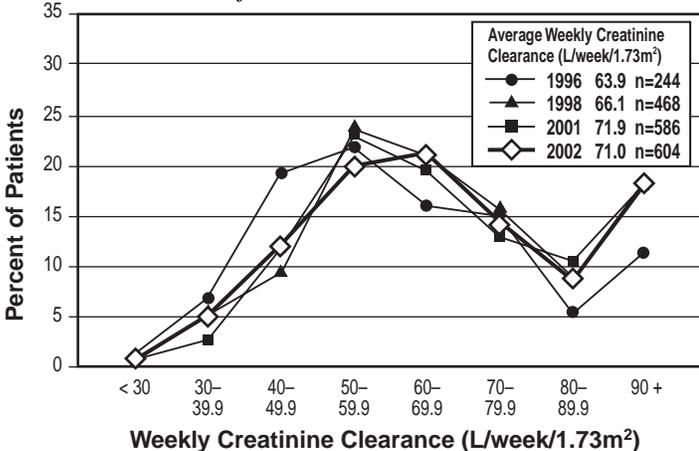


Figure 50: Distribution of Peritoneal Equilibration Test (PET) results for adult peritoneal dialysis patients, October 2001–March 2002. 2002 ESRD CPM Project.

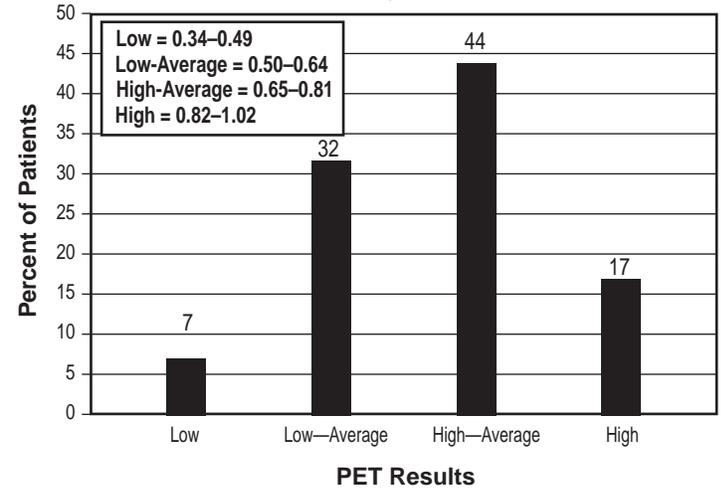
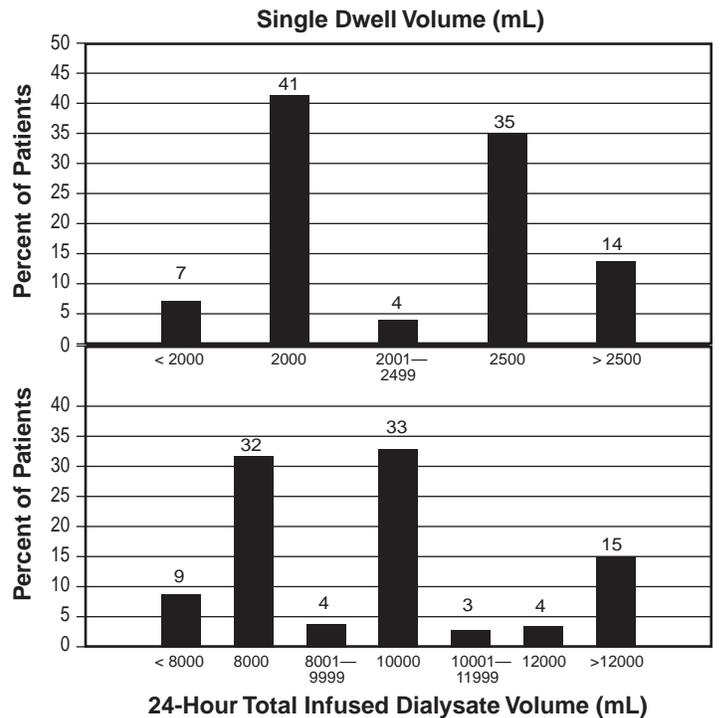


Figure 51: Distribution of single dwell volumes and 24-hour total infused dialysate volumes for adult CAPD patients, October 2001–March 2002. 2002 ESRD CPM Project.



31% of all cycler patients had a single nighttime dwell volume of 2500 mL; 30% had a single nighttime dwell volume of 2000 mL (FIGURE 52). 46% of all cycler patients had a mean of four nighttime exchanges, 23% had a mean of 5 nighttime exchanges, and another 13% had a mean of 3 nighttime exchanges (FIGURE 53).

12% (n = 86) of cycler patients did not have a daytime dwell. 42% of cycler patients with a daytime dwell had a mean single daytime dwell volume of 2000 mL; 20% had a mean single daytime dwell volume of 2500 mL (FIGURE 54). 52% of these patients had one daytime exchange, another 37% had two daytime exchanges (FIGURE 55).

Figure 52: Distribution of mean single nighttime dwell volumes for all adult cycler patients, October 2001-March 2002. 2002 ESRD CPM Project.

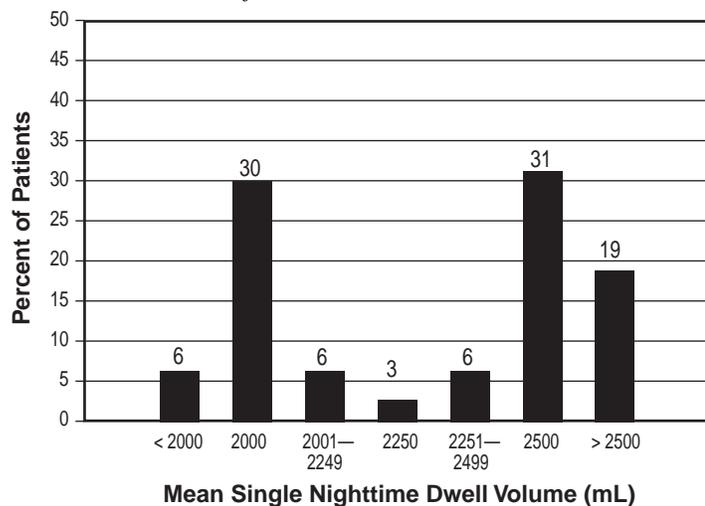


Figure 53: Distribution of the mean number of nighttime exchanges for all adult cycler patients, October 2001-March 2002. 2002 ESRD CPM Project.

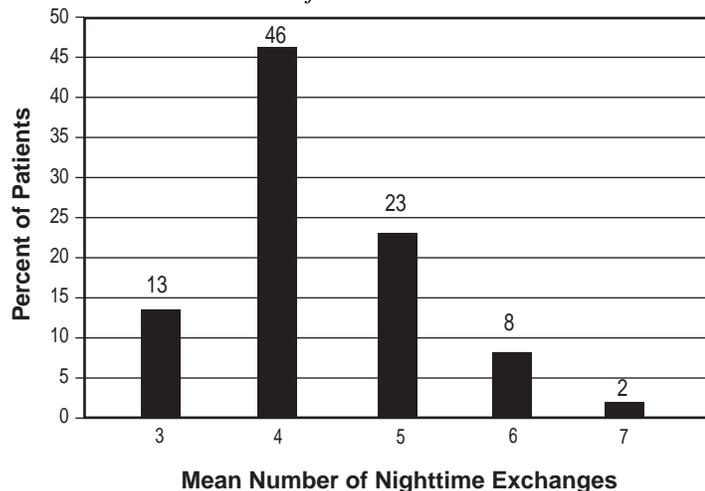
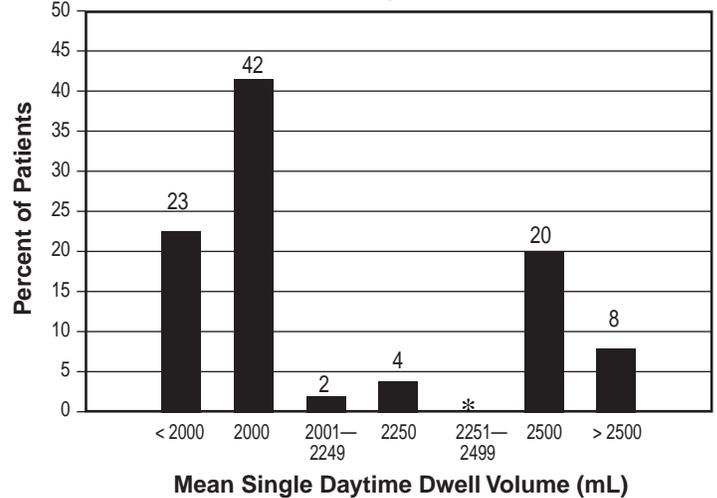
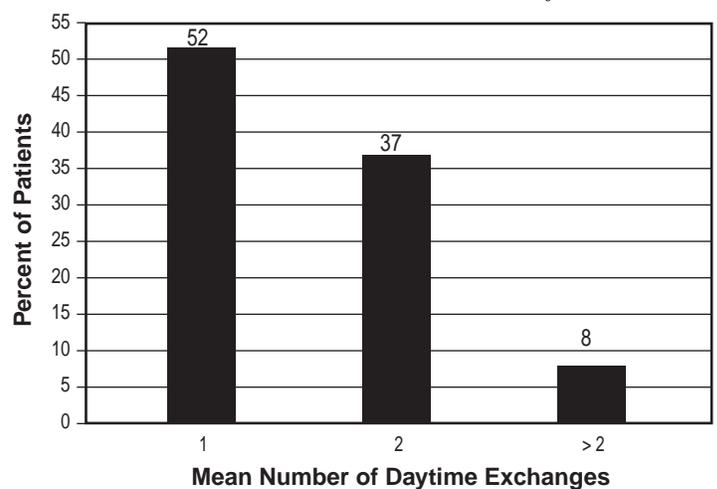


Figure 54: Distribution of mean single daytime dwell volumes for adult cycler patients with a daytime dwell, October 2001-March 2002. 2002 ESRD CPM Project.



*Value suppressed because n ≤ 10.

Figure 55: Distribution of the mean number of daytime exchanges for adult cycler patients with a daytime dwell, October 2001-March 2002. 2002 ESRD CPM Project.



3. CPM and Other Findings for October 2001–March 2002 compared to previous study periods

The adequacy of peritoneal dialysis was reported for 86% of adult peritoneal dialysis patients at least once during the 2001 six-month study period, October 2001–March 2002 (PD Adequacy CPM I), compared to only 82% during the 1999 study period, 83% during the 2000 study period and 85% during the 2001 study period (FIGURE 7). 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 7).

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 2002 study period (FIGURE 56).

Figure 56: Percent of adult peritoneal dialysis patients meeting 1997 NKF-DOQI guidelines for weekly Kt/V_{urea} and weekly creatinine clearance (PD Adequacy CPM III). 2002 ESRD CPM Project.

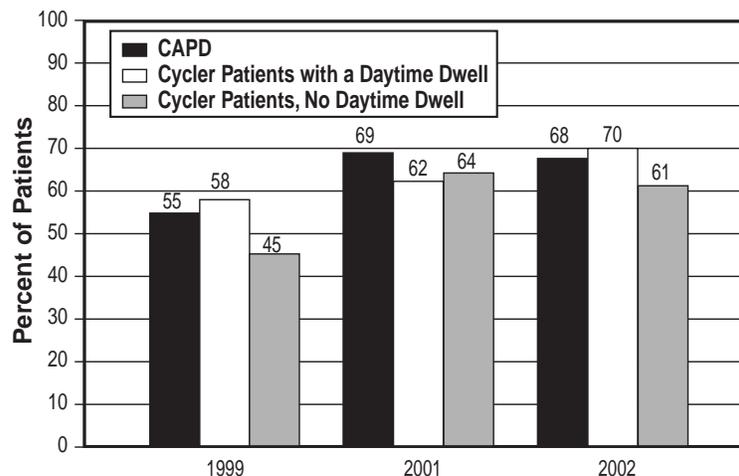


TABLE 19: Percent of adult CAPD patients with mean (\pm SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, by transporter type, October 2001–March 2002. 2002 ESRD CPM Project.

Adequacy Measure	Oct 2000-Mar 2001		Oct 2001-Mar2002	
	High-Avg/High*	Low/Low-Avg	High-Avg/High	Low/Low-Avg
Weekly Kt/V urea				
% meeting NKF-K/DOQI [^]	75%	71%	73%	69%
mean (\pm SD)	2.35 (\pm 0.57)	2.35 (\pm 0.58)	2.41 (\pm 0.71)	2.40 (\pm 0.69)
median	2.26	2.32	2.27	2.23
Weekly Creatinine Clearance				
% meeting NKF-K/DOQI	76%	79%	73%	80%
mean (\pm SD)	83.6 (\pm 29.7)	73.0 (\pm 27.5)	79.9 (\pm 28.4)	77.5 (\pm 32.3)
median	78.6	68.5	72.5	67.6

[^] 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: Low = 0.34-0.49; Low-Average = 0.50-0.64; High-Average = 0.65-0.81; High = 0.82-1.02

TABLE 20: Percent of adult cycler patients with mean (\pm SD) weekly adequacy values meeting 2000 NKF-K/DOQI guidelines and median adequacy values, October 2001–March 2002. 2002 ESRD CPM Project.

Adequacy Measure	Oct 2000-Mar 2001		Oct 2001-Mar2002	
	with daytime dwell	no daytime dwell	with daytime dwell	no daytime dwell
Weekly Kt/V urea				
% meeting NKF-K/DOQI [^]	64%	53%	66%	61%
mean (\pm SD)	2.33 (\pm 0.55)	2.33 (\pm 0.73)	2.33 (\pm 0.55)	2.39 (\pm 0.70)
median	2.24	2.22	2.25	2.29
Weekly Creatinine Clearance				
% meeting NKF-K/DOQI	55%	61%	55%	53%
mean (\pm SD)	71.9 (\pm 25.6)	77.6 (\pm 31.0)	71.0 (\pm 26.3)	76.2 (\pm 31.8)
median	65.7	75.3	65.7	68.1

[^] 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 2001–March 2002

Data to assess three anemia management CPMs were collected in 2002. The time period from which these data were abstracted was October 2001–March 2002.

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

FINDING: For the six-month study period, 36% of the peritoneal dialysis patients who met the inclusion criteria (n=1234) had a mean hemoglobin 11–12.0 gm/dL.

Anemia Management CPM Ila — For all anemic patients (hemoglobin < 11 gm/dL) 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: 74% of the peritoneal dialysis patients who met the inclusion criteria (n=1221) had at least two documented (measured) transferrin saturation values and at least two documented (measured) serum ferritin concentration values during October 2001–March 2002.

Anemia Management CPM Iib — For all anemic patients (hemoglobin < 11 gm/dL) 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: 76% of the adult peritoneal dialysis patients who met the inclusion criteria (n=1221) had at least one documented transferrin saturation ≥ 20% and at least one documented serum ferritin concentration ≥ 100 ng/mL during October 2001–March 2002.

Anemia Management CPM III — All anemic patients (hemoglobin < 11 gm/dL) 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: 31% of the peritoneal dialysis patients who met the inclusion criteria (n=505) were prescribed intravenous iron in at least one of the two-month periods during October 2001–March 2002.

2. Other Anemia Management Findings for October 2001–March 2002

The average (± SD) hemoglobin for adult peritoneal dialysis patients in the sample was 11.8 gm/dL (± 1.4 gm/dL). The distribution of mean hemoglobin values for Black and White patients is depicted in Figure 57. 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 21. 76% of patients had a mean hemoglobin ≥ 11 gm/dL (FIGURE 10, TABLE 21). Significantly more men, Whites, and patients older than 45 years had a mean hemoglobin ≥ 11 gm/dL compared to women, Blacks, and younger patients (TABLE 21). More patients with a mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) had a mean hemoglobin ≥ 11 gm/dL compared to patients with lower mean serum albumin values. Nationally, 63% of patients prescribed Epoetin had a mean hemoglobin 11–12.9 gm/dL.

The prevalence of patients with mean hemoglobin < 9 gm/dL was 3% (FIGURE 57, TABLE 21). The prevalence of patients with mean hemoglobin < 10 gm/dL was 8%. The prevalence of patients with mean hemoglobin < 10 gm/dL was significantly higher in women compared to men, Blacks compared to Whites, for patients 18–44 years old compared to older patients, in patients dialyzing two or more years compared to patients dialyzing less than two years, and in patients with mean serum albumin < 3.5/3.2 gm/dL (BCG/BCP) compared to patients with higher mean serum albumin values (TABLE 21).

Figure 57: Distribution of mean hemoglobin values for adult peritoneal dialysis patients in the US, by race, October 2001–March 2002. 2002 ESRD CPM Project.

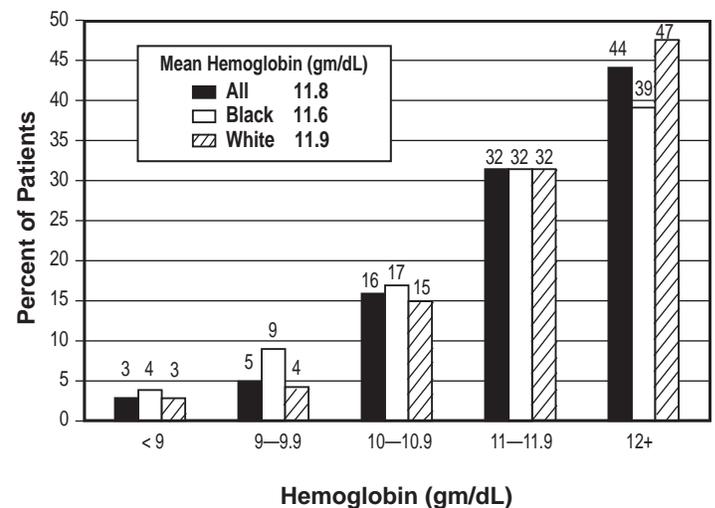


TABLE 21: Mean hemoglobin values (gm/dL) for adult peritoneal dialysis patients, by patient characteristics, October 2001-March 2002. 2002 ESRD CPM Project.

Patient Characteristic	Mean hemoglobin (gm/dL)	Percent of patients with hemoglobin values				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.8	3	5	16	32	44
GENDER						
Men	12.0	2	4	12	32	50
Women	11.6	4	6	19	32	39
RACE						
American Indian/ Alaska Native	11.8	*	*	*	*	48
Asian/Pacific Islander	11.9	*	*	*	36	44
Black	11.6	4	9	17	32	39
White	11.9	3	4	15	32	47
Other/Unknown	11.8	*	*	*	31	40
ETHNICITY						
Hispanic	11.8	*	*	23	25	44
Non-Hispanic	11.8	3	5	15	33	44
AGE GROUP (years)						
18-44	11.4	7	9	18	33	33
45-54	11.8	*	7	18	24	47
55-64	11.9	*	*	16	36	44
65-74	12.0	*	*	12	33	52
75+	12.1	*	*	9	31	57
DIAGNOSIS						
Diabetes Mellitus	11.9	*	6	16	32	45
Hypertension	11.8	*	5	14	30	47
Glomerulonephritis	11.7	5	*	15	34	42
Other/Unknown	11.7	5	5	16	32	42
DURATION of DIALYSIS (years)						
< 0.5	12.0	*	*	14	30	51
0.5-0.9	12.0	*	*	12	34	49
1.0-1.9	11.8	*	4	14	33	45
2.0+	11.6	4	8	18	31	39
MEAN SERUM ALBUMIN (gm/dL)						
≥ 3.5/3.2 (BCG/BCP)^	11.9	2	4	16	29	50
< 3.5/3.2 (BCG/BCP)	11.6	5	7	16	36	36
MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m²)						
≥60	11.9	2	4	13	33	48
<60	11.7	*	5	19	31	43

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

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

*Value suppressed because n ≤ 10.

The average (\pm SD) transferrin saturation for the patients in this sample was 29.2%, (\pm 11.5%) and 83% of patients had mean transferrin saturation \geq 20%. The average (\pm SD) serum ferritin concentration was 400 ng/mL (\pm 359), with 84% of patients having a mean serum ferritin concentration \geq 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 98% of the time when the hemoglobin values were $<$ 9 gm/dL, 99% of the time when the hemoglobin values were between 9-9.9 gm/dL, 95% of the time when hemoglobin values were between 10-10.9 gm/dL and 11-11.9 gm/dL, and 81% of the time when hemoglobin values were \geq 12 gm/dL.

Within the subset of patients who were prescribed Epoetin, 98% were prescribed Epoetin by the SC route; 4% were prescribed Epoetin by the IV route (groups not mutually exclusive). The mean (\pm SD) weekly Epoetin dose for patients prescribed Epoetin by the SC route was 145.4 units/kg/week (\pm 105.6 units/kg/week); by the IV route was 155.0 units/kg/week (\pm 108.9 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 65% of the patients in this sample, and three times over the six-month period for 37% of the patients. Of the patients prescribed iron, 79% were prescribed oral iron and 30% 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), 87% were prescribed either oral or IV iron at least once during the six months, and 42% received some iron three times over the six month study period. 23% of these patients were prescribed IV iron at least once during the six-month study period.

3. CPM and Other Findings for October 2001–March 2002 compared to previous study periods

The percent of peritoneal dialysis patients with mean hemoglobin \geq 11 gm/dL increased from 55% to 76% from the 1998 to the 2002 study periods (FIGURE 10). This improvement was noted for both Black patients (from 38% to 70%) and for White patients (63% to 79%). The average (\pm SD) hemoglobin increased from 11.7 gm/dL (\pm 1.4 gm/dL) during the 2001 study period to 11.8 gm/dL (\pm 1.4 gm/dL) during the 2002 study period (FIGURE 11). 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 \geq 18 years) peritoneal dialysis patients with mean hemoglobin $<$ 10 gm/dL decreased from 18% in the 1998 study period to 8% in the 2002 study period (FIGURE 58).

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 2001–March 2002 study periods.

Figure 59 depicts the trend in Epoetin dosing from the 1998 study period to the 2002 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 60 shows the percent of patients prescribed Epoetin by hemoglobin category for study periods 1998 through 2002.

Figure 58: Percent of adult peritoneal dialysis patients with mean hemoglobin < 10 gm/dL, by race, October 2001–March 2002 compared to previous study periods. 2002 ESRD CPM Project.

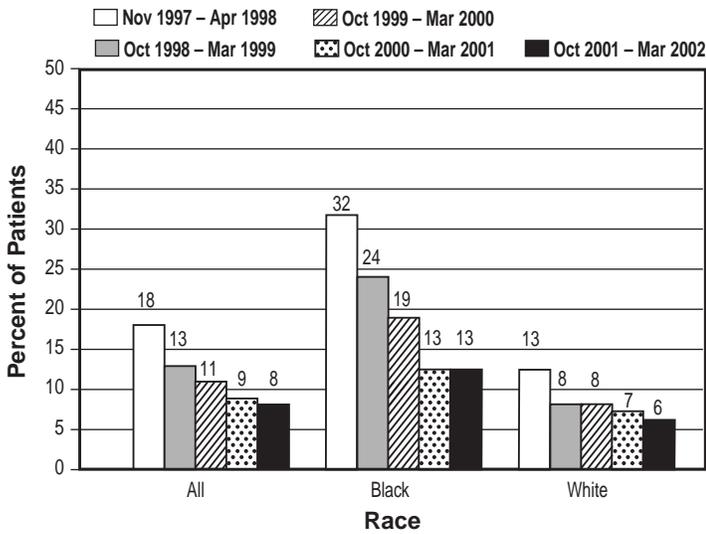


Figure 60: Percent of adult peritoneal dialysis patients who were prescribed Epoetin by hemoglobin category, October 2001–March 2002 compared to previous study periods. 2002 ESRD CPM Project

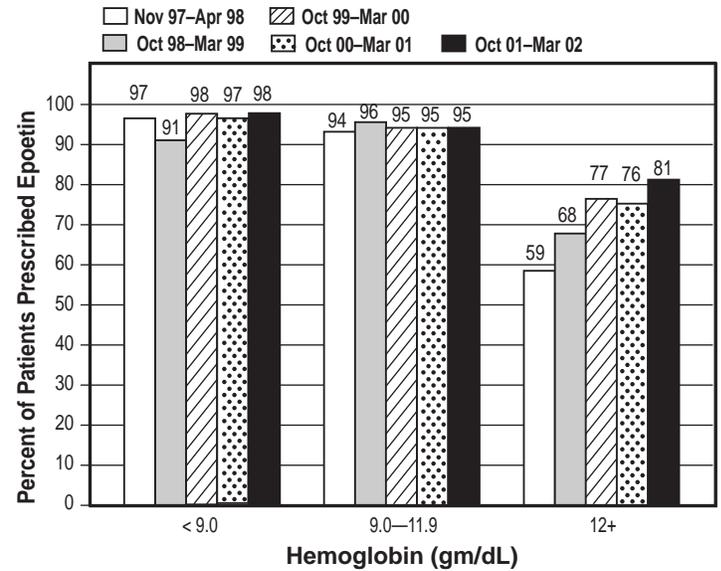


Figure 61: Percent of adult peritoneal dialysis patients with specific anemia management indicators, October 2001–March 2002 compared to selected previous study periods. 2002 ESRD CPM Project

Figure 59: Mean weekly Epoetin dose (units/kg/week) by hemoglobin category for adult peritoneal dialysis patients prescribed Epoetin, October 2001–March 2002 compared to previous study periods. 2002 ESRD CPM Project.

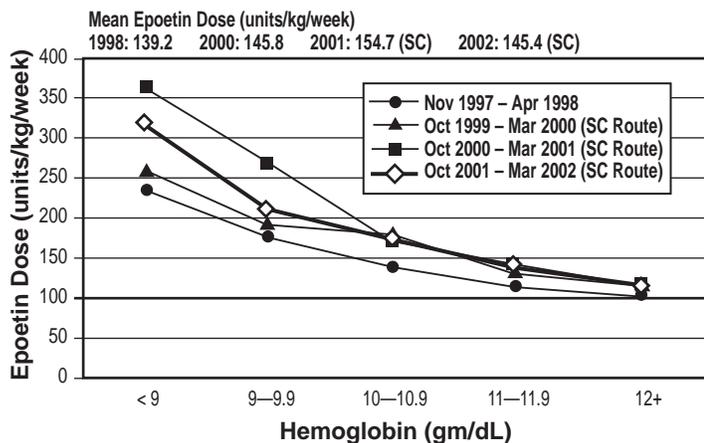


Figure 61 depicts the status of iron stores for the sampled patients for study period 2002 compared to selected previous study periods. Overall, 20% of patients were prescribed IV iron during the 2002 study period compared to 10% during the 1997 study period. 5% of patients had a mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL during the 2002 study period compared to 9% during the 1997 study period.

C. SERUM ALBUMIN

1. Findings for October 2001–March 2002

The mean (\pm SD) serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method ($n=1,190$) was 3.6 gm/dL (± 0.5 gm/dL) and by the BCP method ($n=146$) was 3.2 gm/dL (± 0.5 gm/dL). "Adequate" serum albumin was defined for this report as ≥ 3.5 gm/dL (BCG) or ≥ 3.2 gm/dL (BCP). "Optimal" serum albumin was defined as ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP). Nationally, 19% of patients had a mean serum albumin ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP). 61% of patients had a mean serum albumin ≥ 3.5 gm/dL by the BCG or ≥ 3.2 gm/dL by the BCP method.

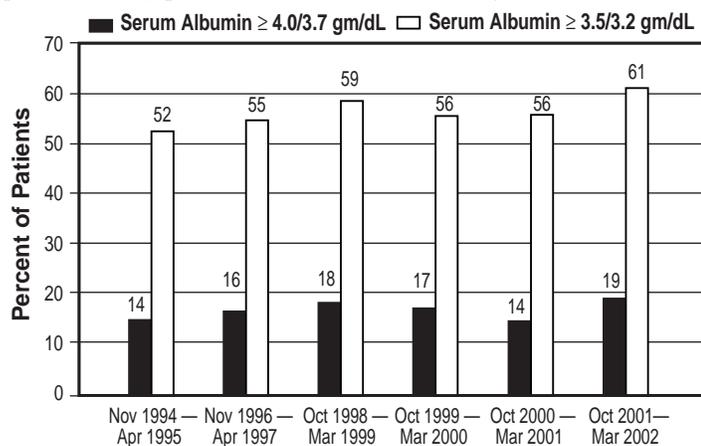
The percent of patients with mean serum albumin defined as either "adequate" or "optimal" by gender, race, ethnicity, age, diagnosis, duration of dialysis, and selected clinical parameters is shown in Table 22. The percent of patients with "optimal" mean serum albumin tended to be higher for men compared 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 gm/dL compared to patients with lower mean hemoglobin values. (TABLE 22).

2. Findings for October 2001–March 2002 compared to previous study periods

Figure 62 shows the percent of patients with mean serum albumin ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP) and the percent of patients with mean serum albumin ≥ 3.5 gm/dL (BCG) or ≥ 3.2 gm/dL (BCP) during the 2002 study period compared to previous study periods.

There was no clinically important change or 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 2002 study period.

Figure 62: Percent of adult peritoneal dialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP), October 2001–March 2002 compared to previous study periods. 2002 ESRD CPM Project.



*Note: BCG = bromcresol green laboratory method
BCP = bromcresol purple laboratory method

TABLE 22: Percent of adult peritoneal dialysis patients with mean serum albumin values $\geq 4.0/3.7$ gm/dL (BCG/BCP)[^] and $\geq 3.5/3.2$ gm/dL (BCG/BCP) in the US, by patient characteristics, October 2001–March 2002. 2002 ESRD CPM Project.

Patient Characteristic	Percent of Patients with Mean Serum Albumin	
	$\geq 4.0/3.7$ gm/dL	$\geq 3.5/3.2$ gm/dL
TOTAL	19	61
GENDER		
Men	24	65
Women	15	58
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	25	72
Black	19	60
White	19	61
Other/Unknown	30	70
ETHNICITY		
Hispanic	21	65
Non-Hispanic	19	61
AGE GROUP (years)		
18-44	29	65
45-54	21	67
55-64	17	64
65-74	13	56
75+	*	45
DIAGNOSIS		
Diabetes mellitus	14	54
Hypertension	21	68
Glomerulonephritis	29	70
Other/Unknown	18	60
DURATION of DIALYSIS (years)		
< 0.5	19	61
0.5-0.9	26	64
1.0-1.9	20	63
2.0+	17	60
MEAN Hgb (gm/dL)		
≥ 11	21	63
< 11	14	54
MEAN WEEKLY CREATININE CLEARANCE (L/WEEK/1.73m²)		
≥ 60	19	60
< 60	21	66

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

* Value suppressed because $n \leq 10$.

V. PEDIATRIC IN-CENTER HEMODIALYSIS PATIENTS

All patients aged < 18 years identified as receiving in-center hemodialysis on December 31, 2001 were included in this study (n=710). 668 patients (94%) of this group met the case definition and were included in the sample for analysis. (See footnote to Table 5 on page 19 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 adequacy of hemodialysis, 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 2001;
- (2) a comparison of core indicator results or findings for October-December 2001 and previous study periods for patients 12 to < 18 years only.

A. ADEQUACY OF HEMODIALYSIS

1. Findings for October–December 2001 (for patients <18 years)

The percent of patients in the sample for analysis with at least one calculated Kt/V measure available (n=626) who received adequate hemodialysis, (defined as a mean Kt/V ≥ 1.2, approximately equivalent to URR ≥ 65% [2]) in the last quarter of 2001 was 87%. The mean (± SD) delivered calculated, single session Kt/V of all pediatric in-center hemodialysis patients in the sample for analysis in the last quarter of 2001 was 1.55 (± 0.32) (FIGURE 63). The distribution of Kt/V values for these patients is shown in Figure 63. Kt/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 71.9% (± 8.1%). 85% of patients had a mean delivered calculated URR ≥ 65%.

FIGURE 63: Distribution of mean delivered calculated, single session Kt/V values for all pediatric (aged <18 years) in-center hemodialysis patients, by age group, October-December 2001. 2002 ESRD CPM Project.

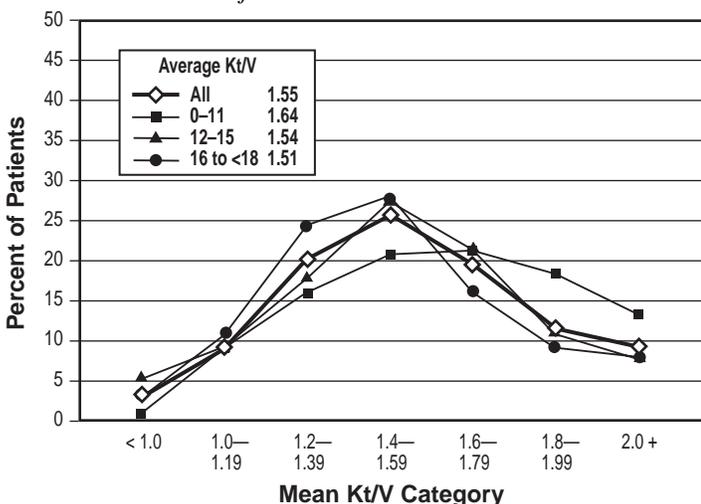


TABLE 23: Mean delivered calculated, single session Kt/V and percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean Kt/V ≥ 1.2, by patient characteristics, October-December 2001. 2002 ESRD CPM Project.

Patient Characteristics	Mean Kt/V	%Kt/V ≥ 1.2
TOTAL	1.55	87
GENDER		
Males	1.51	84
Females	1.60	90
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	1.57	86
Black	1.48	83
White	1.59	90
Other/Unknown	1.61	85
ETHNICITY		
Hispanic	1.58	91
Non-Hispanic	1.54	86
AGE GROUP (years)		
0-4	1.64	96
5-9	1.69	89
10-14	1.57	89
15 to <18	1.50	84
DIALYSIS SESSION LENGTH (minutes)		
<180	1.39	71
180-209	1.49	85
210-239	1.57	91
240+	1.69	93
DURATION of DIALYSIS (years)		
< 0.5	1.34	70
0.5-0.9	1.50	81
1.0-1.9	1.59	92
2.0+	1.62	92
QUINTILE POST-DIALYSIS BODY WEIGHT (kg)		
5.1-28.1	1.68	92
28.2-40.4	1.61	90
40.5-49.0	1.59	92
49.1-62.1	1.46	84
62.2-165.6	1.41	76
ACCESS TYPE		
AV Fistula	1.57	93
AV Graft	1.63	94
Catheter	1.51	81
MEAN Hgb (gm/dL)		
≥ 11	1.56	90
< 11	1.52	82
MEAN SERUM ALBUMIN (gm/dL)		
≥ 3.5/3.2 (BCG/BCP) [^]	1.55	87
< 3.5/3.2 (BCG/BCP)	1.54	84

*Value suppressed because n ≤ 10.

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

The mean Kt/V and the percent of patients with mean Kt/V ≥ 1.2 for gender, race, ethnicity, age, diagnosis, duration of dialysis, quintile of post-dialysis body weight, access type, and mean hemoglobin and serum albumin categories are shown in Table 23. The percent of patients receiving hemodialysis with a mean Kt/V ≥ 1.2 was higher for females than for males, for patients in the lowest quintiles of post-dialysis body weight compared to those patients in the highest quintile, for patients with longer dialysis sessions compared to patients with shorter dialysis sessions, and for patients dialyzing six months or longer than for patients dialyzing less than six months (TABLE 23). A larger percent of patients dialyzed with an AVF or an AV graft compared to those with a catheter had a mean Kt/V ≥ 1.2 (93% and 94% vs. 81%, respectively). A higher percent of patients with a mean hemoglobin ≥ 11 gm/dL had a mean Kt/V ≥ 1.2 compared to patients with a mean hemoglobin < 11 gm/dL (90% vs. 82%, respectively).

The mean (\pm SD) time spent on dialysis per dialysis session was 203 minutes (\pm 30 minutes). The mean time spent on dialysis was longer for Blacks compared to Whites (207 minutes vs. 200 minutes), for patients aged 16 to < 18 years compared to patients aged 12 to 15 years and 0-11 years (210 minutes vs. 201 and 196 minutes respectively), for patients dialyzing two or more years compared to patients dialyzing less than six months (205 minutes vs. 195 minutes), for patients in the highest quintile of post-dialysis body weight compared to those patients in the lowest quintile (218 minutes vs. 194 minutes) and for patients dialyzed with an AVF compared to those patients with an AV graft or catheter access (209 minutes vs. 206 minutes and 200 minutes, respectively).

2. Findings for October-December 2001 compared to previous study periods (for patients 12 to < 18 years)

The average (\pm SD) delivered Kt/V among patients aged 12 to < 18 years increased from 1.47 (\pm 0.38) in October-December

Figure 64: Percent of all pediatric (aged ≥ 12 and < 18 years) male in-center hemodialysis patients with mean delivered calculated, single session Kt/V ≥ 1.2 , by race, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.

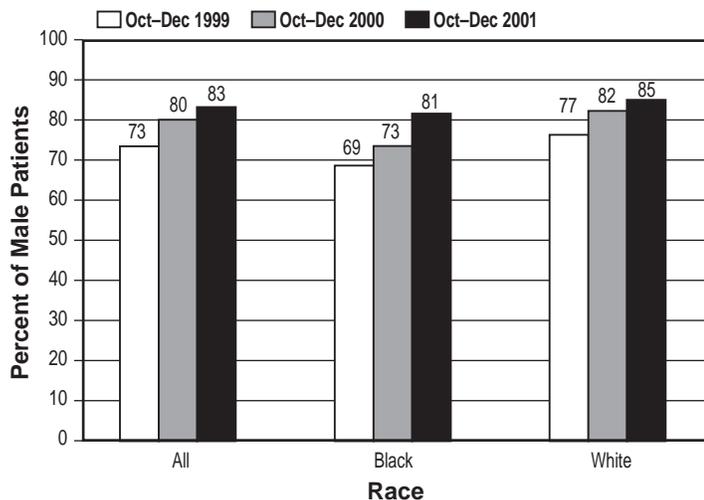
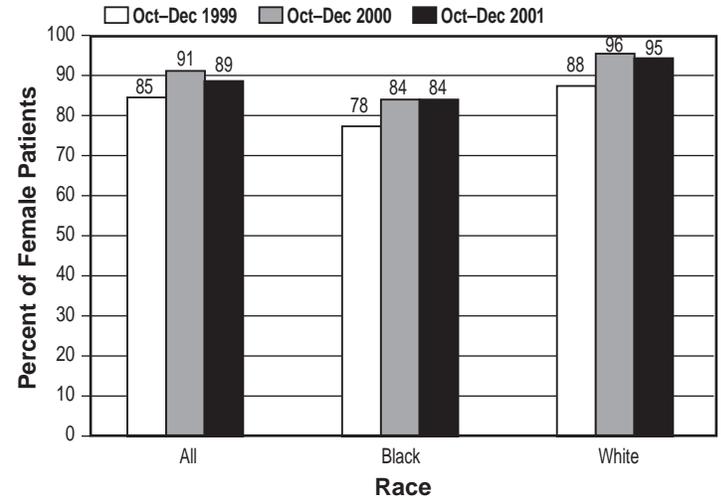


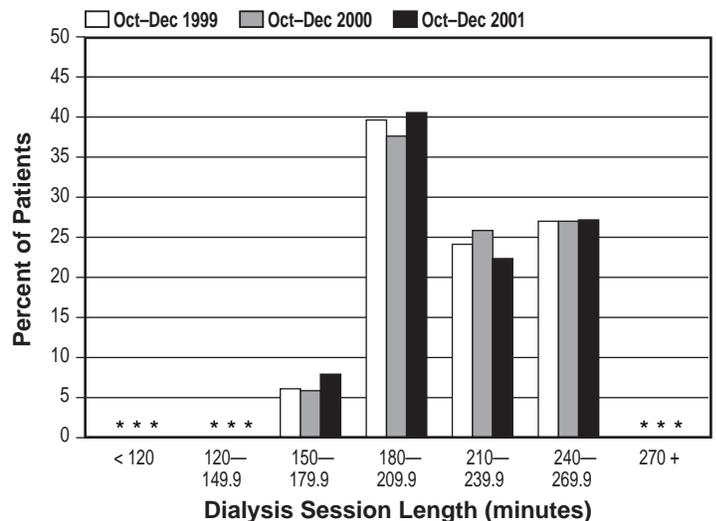
Figure 65: Percent of all pediatric (aged ≥ 12 and < 18 years) female in-center hemodialysis patients with mean delivered calculated, single session Kt/V ≥ 1.2 , by race, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



1999 to 1.52 (\pm 0.32) in October-December 2001 (FIGURE 12). The percent of these patients receiving dialysis with a mean delivered Kt/V ≥ 1.2 increased from 79% in late 1999 to 86% in late 2001. This improvement occurred for both males and females and for White and Black patients (FIGURES 64 and 65).

There was very little change in dialysis session length from late 1999 to late 2001 (FIGURE 66).

Figure 66: Distribution of mean dialysis session length (minutes) for all pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



* Value suppressed because n ≤ 10 .

B. VASCULAR ACCESS

1. Findings for October-December 2001 (for patients <18 years)

26% of patients were dialyzed with an AV fistula (AVF), 18% with an AV graft, and 56% with a catheter during October-December 2001 (TABLE 24). More males, Whites, and patients aged 15 to < 18 years were dialyzed with an AVF compared to females, Blacks, and patients aged 10 to 14 years (TABLE 24).

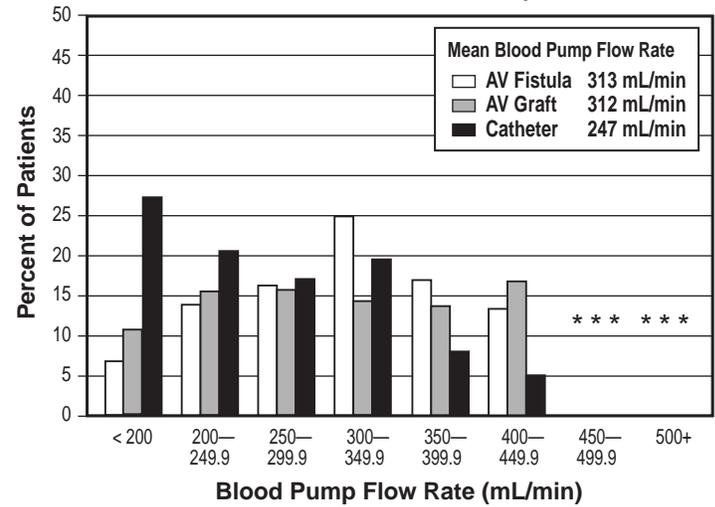
TABLE 24: Vascular access type for all pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2001, by selected patient characteristics. 2002 ESRD CPM Project.

Patient Characteristics	Percent of Patients with		
	AV Fistula	AV Graft	Catheter
TOTAL	26	18	56
GENDER			
Males	30	19	51
Females	21	18	61
RACE			
American Indian/ Alaska Native	*	*	*
Asian/Pacific Islander	*	*	*
Black	19	25	56
White	30	15	55
Other/Unknown	27	13	61
ETHNICITY			
Hispanic	30	13	57
Non-Hispanic	25	20	54
AGE GROUP (years)			
0-4	*	*	97
5-9	*	*	82
10-14	19	22	59
15 to <18	37	19	44
DURATION of DIALYSIS (years)			
< 0.5	10	*	84
0.5-0.9	23	12	65
1.0-1.9	34	19	47
2.0+	30	25	45

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

The mean (± SD) delivered blood pump flow rate 60 minutes into the dialysis session was 313 mL/min (± 83 mL/min) for patients dialyzed with an AVF, 312 mL/min (± 100 mL/min) for patients dialyzed with an AV graft, and 247 mL/min (± 86 mL/min) for patients with a catheter access during October-December 2001 (FIGURE 67).

Figure 67: Distribution of mean delivered blood pump flow rates 60 minutes into the dialysis session for all pediatric (aged < 18 years) in-center hemodialysis patients by access type, October-December 2001. 2002 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 (28). 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 (29).

368 (56%) patients had a catheter as their current access in late 2001. In patients who had catheters for hemodialysis access, no fistula or graft was planned for 49% of the patients, another 24% had no fistula or graft created at the end of 2001, and a fistula or graft had been created but was not ready to cannulate for 14%(TABLE 25). 3% of patients were not candidates for fistula or graft placement as all sites had been exhausted.

Table 25: Reasons for catheter placement in all pediatric (aged < 18 years) in-center hemodialysis patients on their last hemodialysis session during October-December 2001. 2002 ESRD CPM Project.

Reason	n (%)
TOTAL	368 (100)
No fistula or graft surgically planned	181 (49)
Patient size too small for AV fistula/graft	87
Patient preference	66
Renal transplantation scheduled	33
Physician preference	29
Peripheral vascular disease	6
No fistula or graft surgically created at this time	87 (24)
Fistula or graft maturing, not ready to cannulate	50 (14)
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	11 (3)
Other	20 (5)

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

46% of patients (n=305) were dialyzed with a chronic catheter, defined as the continuous use of a catheter 90 days or longer, during October-December 2001.

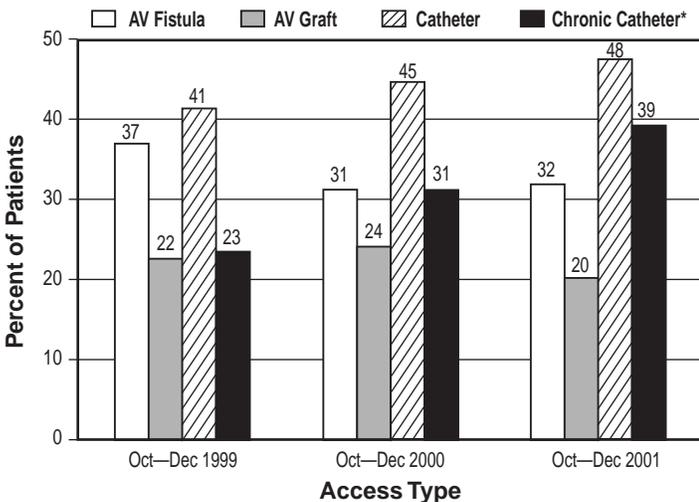
48% of patients (142/295) with an AVF or an AV graft had their access routinely monitored for stenosis. (See Appendix 1 for a complete description of the types of stenosis monitoring.) Within this subset of patients, 51% were monitored with dynamic venous pressure, 17% with the dilution technique, 13% with static venous pressure, 5% with Color-flow Doppler, and 18% had other types of monitoring (groups not mutually exclusive).

2. Findings for October-December 2001 compared to previous study periods (for patients 12 to <18 years)

A lower percent of patients was dialyzed with an AVF in late 2001 compared to late 1999 (32% vs. 37%, respectively) (FIGURES 13 and 68). A higher percent of patients was dialyzed with a catheter in late 2001 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 39% during October-December 2001 (FIGURE 68).

Figure 68: Vascular access type for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients on their last hemodialysis session during the study period, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



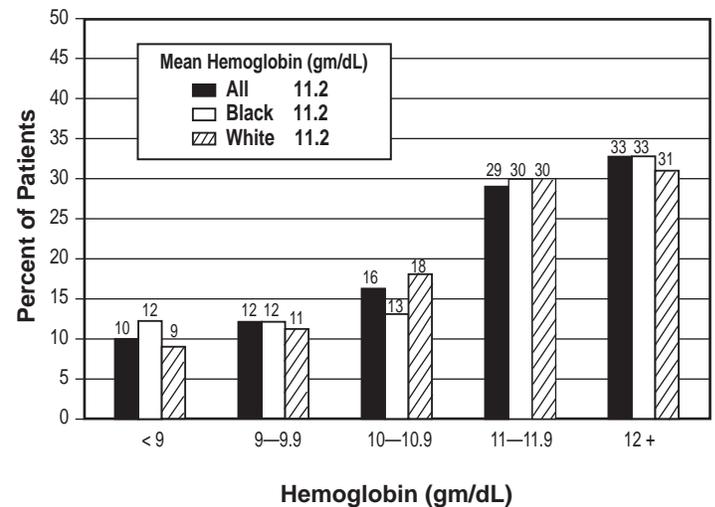
*Chronic catheter use defined as continuous catheter use 90 days or longer.

C. ANEMIA MANAGEMENT

1. Findings for October-December 2001 (for patients <18 years)

The distribution of mean hemoglobin values for all patients, and by race, is shown in Figure 69. The mean (± SD) hemoglobin value for all patients was 11.2 gm/dL (± 1.6 gm/dL). The mean hemoglobin values and distribution of hemoglobin values by gender, race, ethnicity, age, diagnosis, duration of dialysis, access type, and mean Kt/V and serum albumin levels are shown in Table 26. The mean hemoglobin value was lower for patients dialyzing less than six months compared to patients dialyzing six months or longer. Patients with a catheter as their current access had lower mean hemoglobin values compared to patients with either an AVF or an AV graft. Patients with higher mean delivered Kt/V values and higher mean serum albumin values also had higher mean hemoglobin values (TABLE 26).

Figure 69: Distribution of mean hemoglobin values (gm/dL) for all pediatric (aged < 18 years) in-center hemodialysis patients, by race, October-December 2001. 2002 ESRD CPM Project.



The percent of patients with mean hemoglobin < 9 gm/dL was 10%. The percent of patients with mean hemoglobin < 10 gm/dL was 22%. The prevalence of patients with mean hemoglobin < 10 gm/dL was higher in patients dialyzing less than six months compared to those patients dialyzing six months or longer (40% vs. 18%, respectively), and higher in patients with a catheter access compared to patients dialyzed with an AVF (28% vs. 15%). A higher percent of patients with mean Kt/V < 1.2 compared to patients with higher mean Kt/V values had a mean hemoglobin < 10 gm/dL (34% vs. 20%). A higher percent of patients with a mean serum albumin < 3.5/3.2 gm/dL (BCG/BCP) compared to patients with higher serum albumin values had a mean hemoglobin < 10 gm/dL (49% vs. 16%).

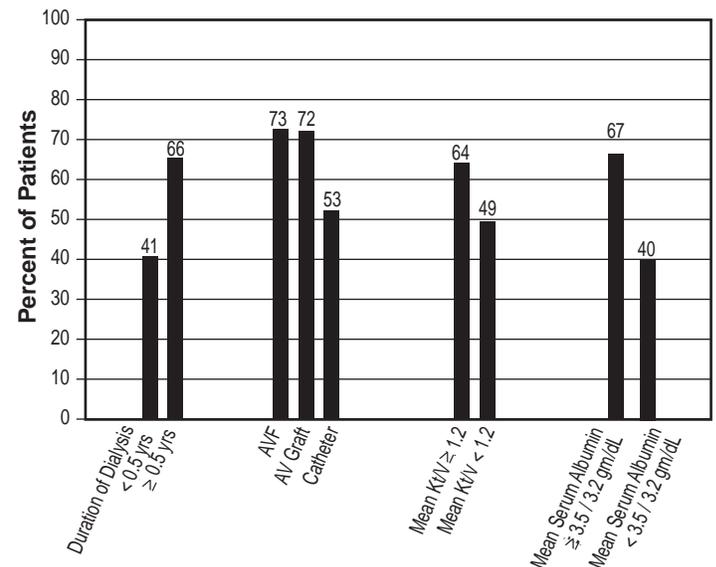
TABLE 26: Mean hemoglobin values (gm/dL) and distribution of hemoglobin values for all pediatric (aged < 18 years) in-center hemodialysis patients, by patient characteristics, October-December 2001. 2002 ESRD CPM Project.

Patient Characteristic	Mean hemoglobin (gm/dL)	Percent of patients with hemoglobin values				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
TOTAL	11.2	10	12	16	29	33
GENDER						
Males	11.2	9	13	15	30	33
Females	11.2	11	10	18	28	33
RACE						
American Indian/ Alaska Native	*	*	*	*	*	*
Asian/Pacific Islander	11.8	*	*	*	*	*
Black	11.2	12	12	13	30	33
White	11.2	9	11	18	30	31
Other/Unknown	11.2	*	*	21	20	34
ETHNICITY						
Hispanic	11.2	6	15	21	30	28
Non-Hispanic	11.2	11	11	15	29	34
AGE GROUP (years)						
0-4	10.7	*	*	*	*	*
5-9	11.0	*	*	27	21	30
10-14	11.1	10	13	16	32	29
15 to < 18	11.4	9	10	14	29	37
DURATION of DIALYSIS (years)						
< 0.5	10.4	22	18	19	26	15
0.5-0.9	11.4	*	13	13	31	36
1.0-1.9	11.5	*	*	17	30	40
2.0+	11.3	8	11	17	29	35
ACCESS TYPE						
AV Fistula	11.7	6	9	12	30	43
AV Graft	11.6	*	10	13	33	39
Catheter	10.9	14	14	20	27	26
MEAN Kt/V						
≥ 1.2	11.3	9	11	15	29	35
< 1.2	10.7	17	17	17	30	19
MEAN SERUM ALBUMIN (gm/dL)						
≥ 3.5/3.2 (BCG/BCP) [^]	11.4	6	10	17	31	36
< 3.5/3.2 (BCG/BCP)	10.4	28	21	12	21	19

* Value suppressed because n ≤ 10.
[^] BCG/BCP = bromocresol green/bromocresol purple laboratory methods.
 Note: Percentages may not add up to 100% due to rounding.

62% of patients had a mean hemoglobin ≥ 11 gm/dL. The percent of patients with mean hemoglobin ≥ 11 gm/dL by selected patient characteristics is shown in Figure 70. A higher percent of patients dialyzing six months or longer, with an AVF or an AV graft as their vascular access, mean Kt/V ≥ 1.2, and mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) achieved a mean hemoglobin ≥ 11 gm/dL compared to patients dialyzing less than six months, patients with a catheter access, a mean Kt/V < 1.2 and mean serum albumin < 3.5/3.2 gm/dL (BCG/BCP).

Figure 70: Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean hemoglobin ≥ 11 gm/dL, by selected patient characteristics and clinical parameters, October-December 2001. 2002 ESRD CPM Project.

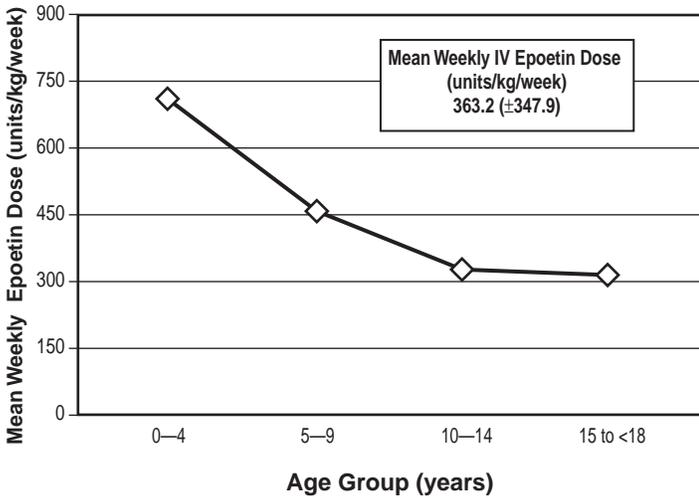


97% of patients were prescribed Epoetin during the study period. Of the patients prescribed Epoetin, 93% were prescribed Epoetin by the IV route; and 8% by the SC route (groups not mutually exclusive). The mean (± SD) weekly Epoetin dose for patients prescribed Epoetin by the IV route was 363.2 units/kg/week (± 347.9 units/kg/week); by the SC route, 295.7 units/kg/week (± 347.7 units/kg/week). Mean prescribed weekly IV Epoetin doses decreased as age increased (FIGURE 71).

The mean (± SD) transferrin saturation for these patients was 28.7% (± 14.2%). 73% of patients had a mean transferrin saturation ≥ 20%. The mean (± SD) serum ferritin concentration was 417 ng/mL (± 416 ng/mL). 78% of patients had a mean serum ferritin concentration ≥ 100 ng/mL. 14% (n=83) 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 68%. The mean administered IV iron dose was 359.1 mg/month (± 288.8 mg/month). For the subset of patients with both mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL (n=54 or 8% of patients), only 65% were prescribed IV iron at least once during the three-month study period.

Figure 71: Mean prescribed weekly IV Epoetin dose (units/kg/week) for all pediatric (aged < 18 years) in-center hemodialysis patients, by age, October-December 2001. 2002 ESRD CPM Project.

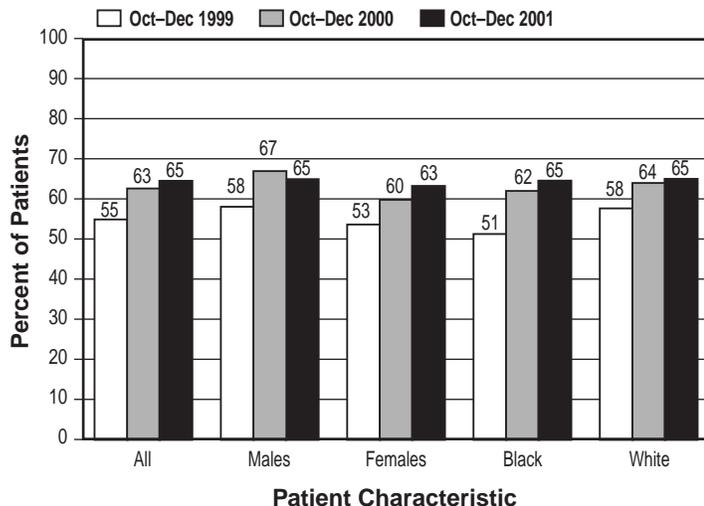


NOTE: SC dose distributions not displayed due to small number of patients

2. Findings for October-December 2001 compared to previous study periods (for patients 12 to <18 years)

The average (\pm SD) hemoglobin from late 1999 to late 2001 among patients 12 to < 18 years increased from 11.0 gm/dL (\pm 1.6 gm/dL) to 11.3 gm/dL (\pm 1.7 gm/dL) (FIGURE 14). The percent of these patients with a mean hemoglobin \geq 11 gm/dL increased from 55% to 65% (FIGURE 72). This improvement occurred for both male and female patients and for Whites and Blacks (FIGURE 72).

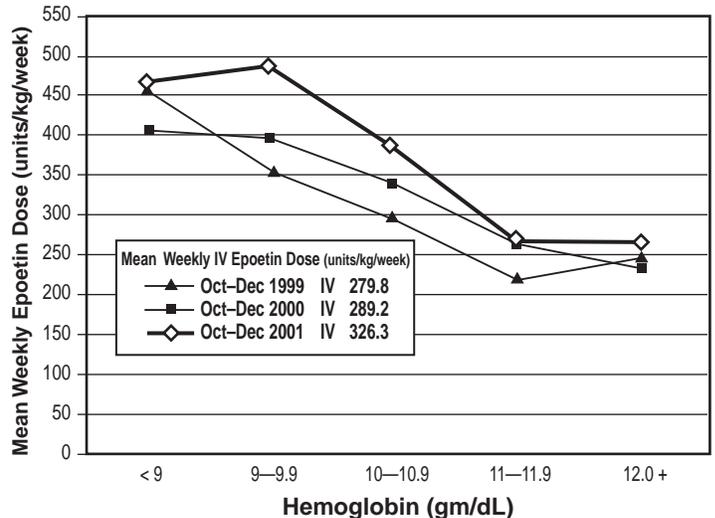
Figure 72: Percent of pediatric (aged \geq 12 and < 18 years) in-center hemodialysis patients with mean hemoglobin \geq 11 gm/dL, by gender and race, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



In addition to the improvement in the percent of patients with mean hemoglobin \geq 11 gm/dL, there was also a decrease in the percent of patients with mean hemoglobin < 10 gm/dL. In October-December 1999, 26% of Black patients and 21% of White patients had a mean hemoglobin < 10 gm/dL, while in October-December 2001, 24% of Black patients and 19% of White patients had a mean hemoglobin < 10 gm/dL.

Figure 73 depicts the trend for increasing prescribed weekly Epoetin dosing (units/kg/week) from late 1999 to late 2001. Prescribed weekly SC Epoetin doses were lower than the prescribed weekly IV Epoetin doses at most hemoglobin categories examined.

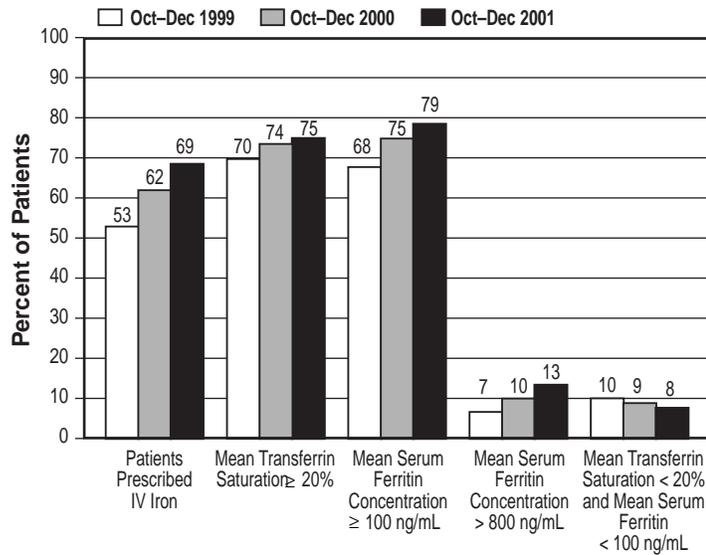
Figure 73: Mean prescribed weekly IV Epoetin dose (units/kg/week) for pediatric (aged \geq 12 and < 18 years) in-center hemodialysis patients, by hemoglobin category, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



NOTE: SC dose distribution not displayed due to small number of patients.

Iron management for pediatric patients aged 12 to < 18 years improved over the two study periods (FIGURE 74). 53% of patients were prescribed IV iron in late 1999 compared to 69% in late 2001. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 38% of patients were prescribed IV iron at least once over the three-month study period in late 1999, compared to 65% in late 2001.

Figure 74: Iron management parameters for pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients, October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



D. SERUM ALBUMIN

1. Findings for October-December 2001 (for patients <18 years)

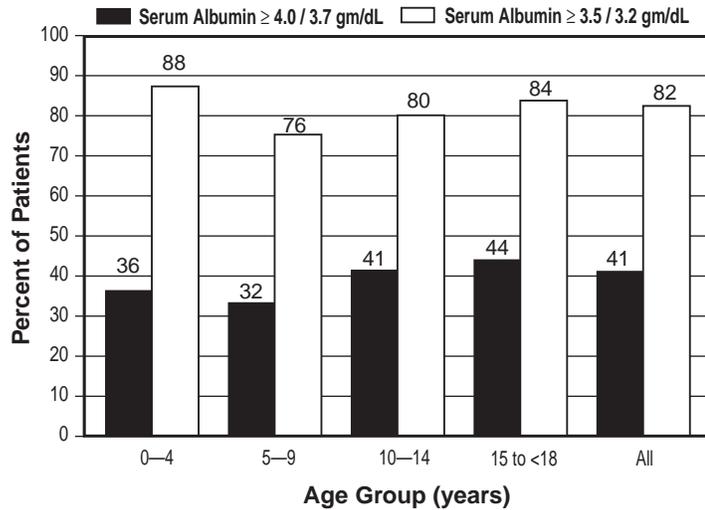
The mean (± SD) serum albumin value for pediatric patients whose value was determined by the BCG method (n=556) was 3.8 gm/dL (± 0.5), and by the BCP method (n=110) was 3.5 gm/dL (± 0.5). “Adequate” serum albumin was defined for this report as ≥ 3.5 gm/dL (BCG) or ≥ 3.2 gm/dL (BCP). “Optimal” serum albumin was defined as ≥ 4.0 gm/dL (BCG) or ≥ 3.7 gm/dL (BCP). Nationally, 41% of patients had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP). 82% of patients had a mean serum albumin ≥ 3.5/3.2 gm/dL (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 Kt/V and hemoglobin categories is shown in Table 27. The percent of patients with “optimal” serum albumin tended to be higher for males compared to females and for Hispanics compared to non-Hispanics. Patients with an AVF access were more likely to have an “optimal” serum albumin compared to patients dialyzed with a catheter. A higher percent of patients with mean hemoglobin ≥ 11 gm/dL had an “optimal” serum albumin compared to patients with lower mean hemoglobin values (TABLE 27). Figure 75 shows the percent of pediatric patients with mean serum albumin ≥ 4.0/3.7 gm/dL and ≥ 3.5/3.2 gm/dL (BCG/BCP) by age group.

TABLE 27: Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin values ≥ 4.0/3.7 gm/dL (BCG/BCP)[^], and ≥ 3.5/3.2 gm/dL (BCG/BCP), by patient characteristics, October-December 2001. 2002 ESRD CPM Project.

Patient Characteristics	Percent of Patients with Mean Serum Albumin	
	≥ 4.0/3.7 gm/dL	≥ 3.5/3.2 gm/dL
TOTAL	41	82
GENDER		
Males	47	83
Females	33	80
RACE		
American Indian/ Alaska Native	*	*
Asian/Pacific Islander	*	80
Black	35	81
White	44	83
Other/Unknown	46	86
ETHNICITY		
Hispanic	51	84
Non-Hispanic	38	81
AGE GROUP (years)		
0-4	36	88
5-9	32	76
10-14	41	80
15 to < 18	44	84
DURATION of DIALYSIS (years)		
< 0.5	35	68
0.5-0.9	42	82
1.0-1.9	45	87
2.0+	41	85
ACCESS TYPE		
AV Fistula	51	88
AV Graft	48	88
Catheter	35	77
Catheter ≥ 90 days	35	80
MEAN Kt/V		
≥ 1.2	41	82
< 1.2	42	78
MEAN Hgb (gm/dL)		
≥ 11	49	88
< 11	29	71

NOTE: Percentages may not add up to 100% due to rounding.
 *Value suppressed because n ≤ 10.
 ^BCG/BCP = bromocresol green/bromocresol purple laboratory methods.

Figure 75: Percent of all pediatric (aged < 18 years) in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP), by age, October-December 2001. 2002 ESRD CPM Project.

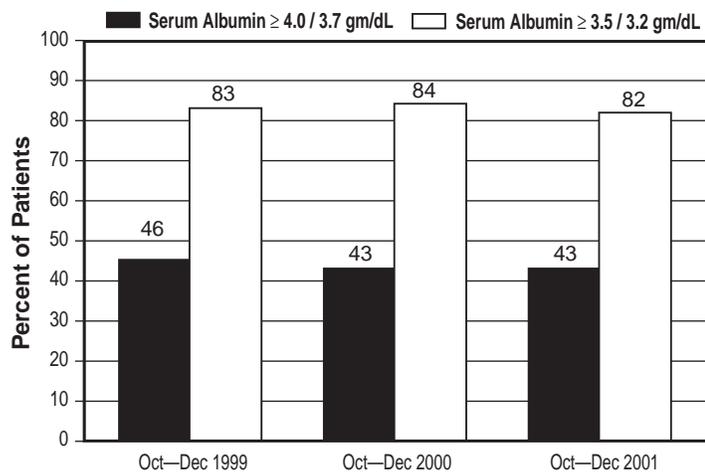


*NOTE: BCG/BCP = bromcresol green/bromcresol purple laboratory methods.

2. Findings for October-December 2001 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 2001 (FIGURE 76).

Figure 76: Percent of pediatric (aged ≥ 12 and < 18 years) in-center hemodialysis patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)* and $\geq 3.5/3.2$ gm/dL (BCG/BCP), October-December 2001 compared to previous study periods. 2002 ESRD CPM Project.



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

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VIII. Appendices

Appendix 1. ESRD Clinical Performance Measures (CPMs) for 2002 Data Collection Effort

Study period for HD patients is Oct, Nov, Dec 2001; for PD patients is Oct, Nov, Dec 2001 and Jan, Feb, Mar 2002

Hemodialysis (HD) Adequacy

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

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

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

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

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

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

Numerator:

Number of patients in denominator with documented monthly adequacy measurements (URR or Kt/V) during the study period. (The study period for HD patients is Oct, Nov, Dec 2001).

Denominator:

All adult (≥ 18 years old) HD patients in the sample for analysis.

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

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

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

Numerator:

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

Denominator:

All adult (≥ 18 years old) HD patients in the sample for analysis.

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

HD Adequacy Guideline 4: Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion). The dialysis care team should deliver a Kt/V of at least 1.2 (single-pool, variable volume) for both adult and pediatric hemodialysis patients. For those using the urea reduction ratio (URR), the delivered dose should be equivalent to a Kt/V of 1.2, i.e., an average URR of 65%; however URR can vary substantially as a function of fluid removal.

Numerator:

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

Denominator:

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

4. HD Adequacy CPM IV: Method of Post-Dialysis Blood Urea Nitrogen (BUN) Sampling.

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

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

Numerator:

Number of facilities in denominator with written policies requiring post-dialysis blood urea nitrogen (BUN) sampling to be done using the Slow Flow/Stop Pump Technique (15-60 seconds after slowing or stopping blood flow) during the study period.

Denominator:

All dialysis facilities included in the sample for analysis.

5. HD Adequacy CPM V: Baseline Total Cell Volume Measurement of Dialyzers Intended for Reuse.

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

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

Numerator:

Facilities in the denominator that during the study period pre-primed 100% of dialyzers intended for reuse.

Denominator:

All facilities in the sample for analysis that reuse dialyzers.

Peritoneal Dialysis (PD) Adequacy

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

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

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

PD Adequacy Guideline 11: Dialysate and Urine Collections (Opinion).

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

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

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

Numerator:

Number of patients in denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period. (The study period for PD patients is Oct, Nov, Dec 2001 and Jan, Feb, Mar 2002).

Denominator:

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

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

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

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

PD Adequacy Guideline 6: Assessing Residual Renal Function (Evidence).

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

PD Adequacy Guideline 9: Estimating Total Body Water and Body Surface Area (Opinion).

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

Watson method:

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

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

Hume method:

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

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

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

For all formulae, Wt is in kg and Ht is in cm:

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

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

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

Numerator:

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

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

* negligible = < 200 mL urine in 24 hours.

Denominator:

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

8. PD Adequacy CPM III: Delivered Dose of Peritoneal Dialysis.

PD Adequacy Guideline 15: Weekly Dose of CAPD (Evidence).

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

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

For NIPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.2 and a weekly total CrCl of at least 66 L/1.73 m².

For CCPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.1 and a weekly total CrCl of at least 63 L/1.73 m².

Numerator:

- For CAPD patients in the denominator, the delivered PD dose was a weekly Kt/V_{urea} of at least 2.0 and a weekly CrCl of at least 60 L/week/1.73 m² or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.
- For cycler patients in the denominator without a daytime dwell (NIPD), the delivered PD dose was a weekly Kt/V_{urea} of at least 2.2 and a weekly CrCl of at least 66 L/week/1.73 m² or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period. For cycler patients in the denominator with a daytime dwell (CCPD), the delivered PD dose was a weekly Kt/V_{urea} of at least 2.1 and a weekly CrCl of at least 63 L/week/1.73 m² or evidence that the prescription was changed according to NKF-K/DOQI recommendations, during the study period.

Denominator:

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

Vascular Access

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

Vascular Access Guideline 29A: Goals of Access Placement-Maximizing Primary Arterial Venous Fistulae (Opinion). Primary arterial venous fistulae (AVF) should be constructed in at least 50% of all new patients electing to receive hemodialysis as their initial form of renal replacement therapy. Ultimately, 40% of prevalent patients should have a native AV fistula. (See Guideline 3, Selection of Permanent Vascular Access and Order of Preference of AV Fistulae).

Numerator:

- a. The number of incident patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period. (The study period for HD patients is Oct, Nov, Dec 2001).
- b. The number of prevalent patients in the denominator who were dialyzed using an AVF during their last HD treatment during the study period.

Denominator:

- a. Incident adult (≥ 18 years old) HD patients (defined as those patients initiating their most recent course of HD on or between Jan 1 and Aug 31, 2000) in the sample for analysis.
- b. Prevalent adult (≥ 18 years old) HD patients in the sample for analysis.

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

Vascular Access Guideline 30A: Goals of Access Placement- Use of Catheters for Chronic Dialysis (Opinion). Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than three months in the absence of a maturing permanent access.

Numerator:

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

Denominator:

All adult (≥ 18 years old) patients in the sample for analysis.

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

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

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

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

Numerator:

The number of patients in the denominator whose AV graft was routinely monitored (screened) for the presence of stenosis during the study period by one of the following methods and with the stated frequency: Color-flow Doppler at least once every 3 months; Static venous pressure at least once every 2 weeks; Dynamic venous pressure every HD session; Dilution technique at least once every 3 months.

Denominator:

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

Anemia Management

12. Anemia Management CPM I: Target Hemoglobin for Epoetin Therapy.

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

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

Numerator:

Number of patients in denominator with documented mean Hgb of 11-12 gm/dL during the study period. (The study period for HD patients is Oct, Nov, Dec 2001 and Oct, Nov, Dec 2001 and Jan, Feb, Mar 2002 for PD patients).

Denominator:

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

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

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

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

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

Chronic renal failure patients should have sufficient iron to achieve and maintain a Hgb of 11 to 12 gm/dL.

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

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

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

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

Numerator:

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

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

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

Denominator:

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

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

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

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

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

Numerator:

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

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

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

Denominator:

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

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

15. Anemia management CPM III: Administration of Supplemental Iron.

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

Supplemental iron should be administered to prevent iron deficiency and to maintain adequate iron stores so that chronic renal failure patients can achieve and maintain a Hgb of 11 to 12 gm/dL in conjunction with Epoetin therapy.

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

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

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

A trial of oral iron is acceptable in the hemodialysis patient, but is unlikely to maintain the transferrin saturation > 20%, serum ferritin concentration > 100 ng/mL, and Hgb at 11-12 gm/dL.

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

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

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

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

Numerator:

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

Denominator:

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

Appendix 2. 2002 CPM Data Collection Form – In-Center Hemodialysis

**IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE
MEASURES DATA COLLECTION FORM 2002**

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

<p>PATIENT IDENTIFICATION</p> <div style="border: 1px solid gray; background-color: #e0e0e0; height: 80px; margin: 10px 0; text-align: center; padding: 10px;"> Place Patient Data Label Here </div>	<p>MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW</p>
<p>12. Patient's Ethnicity (Check appropriate box). <input type="checkbox"/> non-Hispanic <input type="checkbox"/> Hispanic, Mexican American (Chicano) <input type="checkbox"/> Hispanic, Puerto Rican <input type="checkbox"/> Hispanic, Cuban American <input type="checkbox"/> Hispanic, Other <input type="checkbox"/> Unknown</p>	
<p>13. If the above patient information is incorrect make corrections in space above then continue to question 12. Please verify patient's race and verify question 12 above. If patient unknown or was not dialyzed in the unit at any time during OCT 2001 – DEC 2001 return the blank form to the Network.</p>	
<p>14. Patient's height (MUST COMPLETE): _____ inches OR _____ centimeters</p>	
<p>15. Does patient have limb amputation(s): <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>16. Has the patient ever been diagnosed with any type of diabetes? <input type="checkbox"/> Yes (go to 17) <input type="checkbox"/> No (go to 18) <input type="checkbox"/> Unknown (go to 18)</p>	
<p>17. If question 16 was answered YES, is the patient currently taking medications to control the diabetes? o Yes o No (go to 18) If YES, is the patient using insulin? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Individual Completing Form (Please print):</p> <p>First name: _____ Last name: _____ Title: _____</p> <p>Phone number: (_____) _____ - _____ Fax number: (_____) _____ - _____</p>	

INSTRUCTIONS FOR COMPLETING THE IN-CENTER HEMODIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002

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

- | | |
|--|---|
| <ul style="list-style-type: none"> 1. LAST and first name. 3. SOCIAL Security Number (SSN). 5. SEX (1=Male; 2=Female; 3=Unknown). 7. PRIMARY cause of renal failure by HCFA-2728 code. 9. ESRD Network number.
Do not make corrections to this item | <ul style="list-style-type: none"> 2. DATE of birth (DOB) as MM/DD/YYYY. 4. HEALTH Insurance Claim Number (HIC). 6. RACE (1=American Indian/Alaska Native; 2=Asian; 3=Black; 4=White; 5=Unknown; 6=Pacific Islander; 7=Mid East Arabian; 8=Indian Subcontinent; 9=Other Multiracial). 8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis. 10. Facility's Medicare provider number. 11. The most RECENT date this patient returned to hemodialysis following:
transplant failure, an episode of regained kidney function, or switched modality. |
|--|---|
- 12. Patient's Ethnicity. Please verify the patient's ethnicity and check appropriate box.
 - 13. Review the patient and facility-specific information contained on the pre-printed label. Please verify the patient's race, item 6 above. If any of the information is incorrect write corrections in the space to the right of the label. If the patient is unknown or if the patient was not dialyzed in the unit at any time during OCT 2001 through DEC 2001, send the blank form back to the ESRD Network office with the name and address of the facility providing services to this patient on December 31, 2001, if known.
 - 14. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank. You may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height and check YES for item 15.
 - 15. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but **check YES if this patient has had a below-knee, below-elbow, or more proximal (extensive) amputation.**
 - 16. Check either "Yes", or "No", or "Unknown" to indicate if the patient has ever been diagnosed with any type of diabetes. If YES, proceed to question 17.
 - 17. If the answer to 16 is YES, please check either "Yes" or "No" to indicate if the patient is currently taking medications to control the diabetes. If the answer to 17 is YES, please check either "Yes" or "No" to indicate if the patient is currently using insulin.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)			
<p>LAB DATA. The following data are requested for OCT, NOV, & DEC 2001. For each question, use the FIRST LAB VALUES OF THE MONTH. Do not leave any questions blank. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: <u>NF</u> if Not Found. <u>HOSP</u> if patient was hospitalized during the month. <u>TRANS</u> if patient was absent during the month.</p>			
<p>18. ANEMIA MANAGEMENT: Enter the FIRST Hemoglobin (Hgb) determined by the laboratory for EACH MONTH: OCT, NOV, DEC 2001. Also enter the appropriate erythropoietic prescription/dose information prior to the first monthly Hgb. Enter the first monthly Serum Ferritin concentration and Transferrin Saturation. Enter the appropriate iron prescription/dose information for each month.</p>			
	OCT 2001	NOV 2001	DEC 2001
A. First monthly pre-dialysis laboratory hemoglobin (Hgb):	_____ . _____ g/dL	_____ . _____ g/dL	_____ . _____ g/dL
B.1. Was there a prescription for Epoetin during the seven days immediately before the Hgb in 18A. was drawn?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>For patients prescribed Epoetin:</p> B.2. What was the PRESCRIBED Epoetin dose in units for each treatment during the seven days immediately BEFORE the Hgb in 18A. was drawn? (See instructions on page 4).	_____ units/tx _____ units/tx _____ units/tx	_____ units/tx _____ units/tx _____ units/tx	_____ units/tx _____ units/tx _____ units/tx
B.3. How many times per week was Epoetin prescribed?	_____ x per week	_____ x per week	_____ x per week
B.4. What was the prescribed route of administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC
C.1. Was there a prescription for Darbepoetin (Aranesp™) during the month immediately before the Hgb in 18A. was drawn?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>For patients prescribed Darbepoetin:</p> C.2. What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A. was drawn? (See instructions on page 4 and 5).	_____ mcg/month	_____ mcg/month	_____ mcg/month
C.3. How many times per month was Darbepoetin prescribed?	_____ x per month	_____ x per month	_____ x per month
C.4. What was the prescribed route of administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC
D. First monthly Serum Ferritin concentration:	_____ ng/mL	_____ ng/mL	_____ ng/mL
E. First monthly Transferrin Saturation:	_____ %	_____ %	_____ %
F. Was iron prescribed at any time during the month?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19)
G. If yes, what was the prescribed route of iron administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> PO	<input type="checkbox"/> IV <input type="checkbox"/> PO	<input type="checkbox"/> IV <input type="checkbox"/> PO
H. If the patient was prescribed IV iron, what was the dose of IV iron administered during the month?	_____ mg/month	_____ mg/month	_____ mg/month

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)			
19. SERUM ALBUMIN: Enter the FIRST monthly serum albumin FOR EACH MONTH: OCT, NOV, DEC 2001. Check the method used (green or purple) by the lab to determine the serum albumin. If method unknown, please call lab to find out. Do not leave blank.			
	OCT 2001	NOV 2001	DEC 2001
A. First monthly serum albumin:	_____ . _____ gm/dL	_____ . _____ gm/dL	_____ . _____ gm/dL
B. Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP
20. ADEQUACY: Enter the first monthly pre-and post-dialysis BUN FOR EACH MONTH: OCT, NOV, DEC 2001. The pre-and post-dialysis BUNs must be drawn on the same day of the month. Also, enter the patient's actual DELIVERED time on dialysis when the BUNs were drawn and the <u>code</u> for the name of the dialyzer used at the time the BUNs were drawn (see attached chart for the dialyzer codes.).			
	OCT 2001	NOV 2001	DEC 2001
A. How many times per week was this patient scheduled to receive dialysis?	_____ times per week	_____ times per week	_____ times per week
B. First monthly Pre-dialysis BUN:	_____ mg/dL	_____ mg/dL	_____ mg/dL
C. First monthly Post-dialysis BUN:	_____ mg/dL	_____ mg/dL	_____ mg/dL
D. First monthly recorded URR	_____ . _____ %	_____ . _____ %	_____ . _____ %
E. First monthly recorded Kt/V (If both URR and Kt/V were recorded, answer both 20D & 20E).	_____ . _____	_____ . _____	_____ . _____
F.1. Method used to calculate Kt/V	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Equilibrated <input type="checkbox"/> Derived from URR (no pt. weights) <input type="checkbox"/> Other/Unknown_____	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Equilibrated <input type="checkbox"/> Derived from URR (no pt. weights) <input type="checkbox"/> Other/Unknown_____	<input type="checkbox"/> UKM <input type="checkbox"/> Daugirdas II <input type="checkbox"/> Equilibrated <input type="checkbox"/> Derived from URR (no pt. weights) <input type="checkbox"/> Other/Unknown_____
F.2. Is residual urine function used to calculate Kt/V?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
G. Patient's PRE- & POST-dialysis weight when above BUNs were drawn: (<i>Circle either lbs or kgs</i>).	Pre: _____ lbs / kgs Post: _____ lbs / kgs	Pre: _____ lbs / kgs Post: _____ lbs / kgs	Pre: _____ lbs / kgs Post: _____ lbs / kgs
H. Actual DELIVERED time on dialysis at session when BUNs drawn:	____ hrs ____ min	____ hrs ____ min	____ hrs ____ min
I. Delivered blood pump flow rate @ 60 min. from the start of the dialysis session at which BUNs are drawn.	_____ mL/min	_____ mL/min	_____ mL/min
J. Code for dialyzer used for dialysis at session when BUNs drawn: (See chart).	_____	_____	_____

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)	
21. VASCULAR ACCESS: Please answer the following questions concerning the patient's vascular access.	
A. What type of access was used on the last hemodialysis session on or between 10/1/2001 and 12/31/2001 at the patient's primary in-center facility? <input type="checkbox"/> AV Fistula (go to questions 21C1&C2) <input type="checkbox"/> Catheter (go to questions 21B1&B2) <input type="checkbox"/> Unknown (go to question 22) <input type="checkbox"/> Synthetic Graft (go to questions 21C1&C2) <input type="checkbox"/> Port Access (go to question 21B1&B2) <input type="checkbox"/> Bovine Graft (go to questions 21C1&C2) <input type="checkbox"/> Other _____ (go to question 22)	
B.1. Reason for catheter or port access: <input type="checkbox"/> Fistula or graft maturing, not ready to cannulate <input type="checkbox"/> No fistula or graft surgically planned (check all that apply) <input type="checkbox"/> Temporary interruption of fistula or graft due to clotting or revisions <input type="radio"/> Peripheral vascular disease <input type="checkbox"/> All fistula or graft sites have been exhausted <input type="radio"/> Patient size too small for AV fistula or graft <input type="checkbox"/> No fistula or graph surgically created at this time <input type="radio"/> Renal transplantation scheduled <input type="checkbox"/> Other _____ <input type="radio"/> Patient preference <input type="checkbox"/> Other _____ <input type="radio"/> Provider preference	
B.2. Had a catheter or port access been used exclusively for the past 90 days or longer ?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
C.1. Was routine surveillance for the presence of stenosis performed between 10/1/01 and 12/31/01?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to question 22)
C.2. If answer to question 21C1 is "Yes," please check all methods of surveillance (below) that were utilized. (See instructions on page 6). <input type="checkbox"/> Color-Flow Doppler at least once between 10/1/01 and 12/31/01 <input type="checkbox"/> Static Venous Pressure at least once every 2 weeks between 10/1/01 and 12/31/01 <input type="checkbox"/> Dynamic Venous Pressure every HD session between 10/1/01 and 12/31/01 <input type="checkbox"/> Dilution Technique at least once between 10/1/01 and 12/31/01 <input type="checkbox"/> Other _____	
22. Did the patient FIRST start hemodialysis during January 1, 2001-August 31, 2001 (see item #8 on page 1)? DO NOT include patients who have changed modality, had a newly failed transplant, or returned after an episode of regained kidney function (See instructions on page 6). <input type="checkbox"/> Yes (answer 22.A-B) <input type="checkbox"/> No (collection form completed)	
A. What type of access was in use at the Initiation of a maintenance course of hemodialysis (See item #8 on page 1)? <input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Port Access <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown	
B. What type of access was in use 90 days later? <input type="checkbox"/> AV Fistula <input type="checkbox"/> Synthetic Graft <input type="checkbox"/> Bovine Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Port Access <input type="checkbox"/> Other _____ <input type="checkbox"/> Unknown	
INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 22 (Continued from page 1): To answer questions 18 through 22, review the patient's clinic or facility medical record for OCT 1, 2001 through DEC 31, 2001. Do not leave any items blank. Enter the following if the information cannot be located: <u>NF</u> if not found, <u>HOSP</u> if hospitalized during the entire time period, <u>TRANS</u> if the patient was absent during the entire time period.	
18A: Enter the patient's FIRST MONTHLY pre-dialysis hemoglobin (Hgb) value determined by the laboratory for EACH month: OCT, NOV, and DEC 2001.	
18B.1-B.4: Check the appropriate box to indicate if there was a prescription for Epoetin during the seven days IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A. For patients prescribed Epoetin, enter the PRESCRIBED Epoetin DOSE in units for each treatment during the seven days IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A, even if the patient did not receive the Epoetin dose. Include any prescribed dose missed due to treatment skipped or error, etc., when entering each treatment dose. Enter 0 units if the patient was on "Hold" for a treatment (for the purposes of this collection, a "hold" order will be considered a 0 unit prescribed dose). If Epoetin is prescribed less frequently than every treatment, leave the units/tx space blank to indicate one or two doses per the seven day period. Enter the number of times per week that Epoetin was prescribed. Check the appropriate space to indicate the prescribed route of administration for Epoetin (intravenous [IV] or subcutaneous [SC]). If patient received Epoetin IV and SC, please check both spaces.	
18C.1-C.4: Check the appropriate box to indicate if there was a prescription for Darbepoetin (Aranesp™) during the month IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A. For patients prescribed Darbepoetin, enter the PRESCRIBED DARBEPOETIN DOSE in micrograms per month (mcg/month) during the month IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A, even if the patient did not receive the Darbepoetin dose. Include	

(Continued on page 5)

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)
any prescribed dose missed due to dose skipped or error, etc., when entering the dose. Enter 0 mcg/month if the patient was on "Hold" (for the purposes of this collection, a "hold" order will be considered a 0 mcg/month prescribed dose). Enter the number of times per month that Darbepoetin was prescribed. Check the appropriate space to indicate the prescribed route of administration for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient received Darbepoetin IV and SC, please check both spaces.
18D: Enter the patient's FIRST MONTHLY serum ferritin concentration recorded in EACH month for which data were available during the months of OCT, NOV, and DEC 2001. If a serum ferritin concentration test was not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).
18E: Enter the patient's FIRST MONTHLY transferrin saturation recorded in EACH month for which data were available during the months of OCT, NOV, and DEC 2001. If a transferrin saturation test was not performed monthly, enter the value for the month when performed and record "NP" for the other month(s).
18F: Check either "Yes" or "No" to indicate if iron was prescribed at any time during the months of OCT, NOV, and DEC 2001. If there was no prescription for iron go to question 19.
18G: If the answer to 18F is "Yes," please check the appropriate space to indicate the route of iron administration (intravenous [IV] or by mouth [PO]) each month for the months of OCT, NOV, and DEC 2001. If patient received iron by mouth and IV, please check both spaces.
18H: If the patient was prescribed IV iron, enter the dose of IV iron (in mg) that was administered during the month.
19A: Enter the patient's FIRST serum albumin value recorded EACH month for OCT, NOV, and DEC 2001.
19B: Check the method used by the laboratory to determine the serum albumin values (bromocresol green or bromocresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information. DO NOT LEAVE THIS QUESTION BLANK.
20A: Please indicate the number of dialysis sessions this patient was scheduled to receive per week in OCT, NOV, and DEC 2001. If the prescription varied during a month, enter the prescription in effect for the first week of that month.
20B and 20C: Enter the patient's FIRST pre-and post-dialysis BUN values recorded EACH month for OCT, NOV, and DEC 2001. The pre-and post-dialysis BUN values must be drawn on the same date. If pre- and post-dialysis BUNs are only performed quarterly, enter the values for the month when performed and record "NP" (i.e., not performed) for the other two months.
20D and 20E: Enter the patient's FIRST URR and/or Kt/V recorded each month for OCT, NOV, and DEC 2001. If both Kt/V and URR were recorded for this patient, please enter both.
<p>20F.1: Check the box which describes the method used by your dialysis center or its designee to calculate Kt/V.</p> <p>Formal UKM: Please check the box marked "UKM" if you know that your facility (or designee) monitors adequacy of dialysis using the method that provides a single-pool, variable volume Kt/V. This method requires a computer (or special calculator) to calculate the Kt/V value and <i>all</i> of the following datapoints: pre- and post-dialysis BUN for the first treatment of the week, the pre-dialysis BUN for the second treatment of the week, and pre- and post-dialysis weights for the first treatment of the week, the actual treatment time, and the actual in vivo clearance of the dialyzer as measured in the dialysis unit (not the in vitro clearance reported by the manufacturer).</p> <p>Daugirdas II: Please check the box marked "Daugirdas II" if you know that your facility (or designee) monitors adequacy using a method that provides a natural log single-pool Kt/V. This method requires the following data points: pre- and post-BUN, actual treatment time in hours, pre- and post-dialysis weight in kg or post-dialysis weight in kg and ultrafiltration (UF) volume in liters. The formula is:</p> $Kt/V = -\ln(\text{post-BUN}/\text{pre-BUN} - 0.008 \times t) + (4 - 3.5 \times \text{post-dialysis BUN}/\text{pre-dialysis BUN}) \times \text{UF}/\text{post-dialysis weight}.$ <p>Equilibrated: Please check the box marked "Equilibrated" only if the post-dialysis BUN was drawn at least 30 minutes after the end of the dialysis treatment. Do not mark this box if your facility or designee uses a formula to calculate an equilibrated Kt/V from a single-pool Kt/V.</p> <p>Derived from URR (no pt. weights): Please check the box marked "Derived from URR" only if the Kt/V is calculated only from the pre- and post-dialysis BUN values and no other patient or treatment data (including no pt. weights). Check this box if a Kt/V value is derived only from pre- and post-dialysis BUN levels, such as a Kt/V value derived by the Basile or Jindal equations. This result may be calculated and provided by your laboratory along with other laboratory results.</p> <p>Other/Unknown: Please check the "Other/Unknown" box if you do not use any of the adequacy methods described above OR you do not know the method used. If using another method and you know what it is, please write that method in the space provided.</p>
20F.2: Check the appropriate box to indicate whether residual urine function is used to calculate Kt/V.
20G: Enter the patient's PRE- and POST-dialysis weight at the session when the pre- and post-dialysis BUN levels were drawn. Circle either lbs or kgs as appropriate.

IN-CENTER HEMODIALYSIS (HD) CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)
20H: Enter the patient's ACTUAL DELIVERED time on dialysis during the session when the BUN levels were drawn. DO NOT ENTER THE PRESCRIBED TIME ON DIALYSIS. If using finish time minus start time to calculate actual delivered time on dialysis, deduct time for any interruptions in dialysis which occurred.
20I: Please record the delivered blood pump flow rate in mL/min at 60 min. from the start of the hemodialysis session. Do not record the prescribed blood pump flow rate or the highest achieved blood pump flow rate.
20J: Using the enclosed Dialyzer Code Chart, enter the code for the dialyzer used on the date the blood samples were drawn for the pre- and post-dialysis BUNs in OCT, NOV, and DEC 2001. If the dialyzer used is not listed on the chart, enter the code for "other" (9999).
21A: Check the appropriate space to indicate type of vascular access used on last hemodialysis session on or between OCT 1, 2001 and DEC 31, 2001 at the patient's primary in-center facility. Exclude dialysis sessions performed at temporary facilities because of holiday travel or hospitalizations. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).
21B.1 and 21B.2: Complete 21B.1 and 21B.2 only if vascular access checked in question 21A was a catheter or port access .
21B.1: If the vascular access marked for question 21A was a catheter or port access, indicate in the appropriate space the reason for the catheter or port access .
21B.2: If the vascular access marked for question 21A was a catheter or port access, indicate in the appropriate space if one or more catheters or port accesses had been used continuously in this patient for the past 90 days or longer between OCT 1, 2001 and DEC 31, 2001.
21C.1 and 21C.2: Complete 21C.1-21C.2 only if vascular access used on most recent dialysis session was an AV fistula, synthetic graft or bovine graft .
21C.1: If the vascular access marked for question 21A was an AV fistula, synthetic graft or bovine graft, indicate if there was routine surveillance for the presence of stenosis between OCT 1, 2001 and DEC 31, 2001. Routine surveillance is the sequential measurement of access flow or venous pressure. The appropriate interval between sequential measurements depends on the technique used to monitor for stenosis, and is described below. For the purpose of this review , techniques used to monitor access flow include (a) one of the dilution methods in which the needles are reversed and recirculation is deliberately induced, or (b) conventional Color-Flow Doppler. In the former, the dilution indicator may be a change in (1) the velocity of ultrasound in blood, (2) hemoglobin/hematocrit, (3) temperature, (4) solute concentration, or (5) conductivity. Pump blood flow must be accurately measured to use this technique. Techniques used to monitor venous pressure include dynamic and static venous dialysis pressures. Dynamic venous pressure monitoring uses low blood pump flow rates usually set at 200 mL per minute. Static pressure monitoring is performed at zero blood pump flow. If access flow was monitored, it should have been measured on a regular basis by one of the available dilution techniques or by conventional Color-Flow Doppler at a minimum frequency of once every three months . If dynamic venous pressure was monitored it should have been measured at every hemodialysis session . If static venous pressure was monitored it should have been measured at a minimum frequency of once every two weeks . For the purpose of this review , clinical assessment such as prolonged bleeding after needle withdrawal, or altered characteristics of thrill or bruit, as well as dialysis adequacy measurements using Kt/V or URR, supplement but do NOT constitute monitoring techniques. For the purpose of this review , recirculation methods do NOT constitute monitoring for the presence of AV graft stenosis.
21C.2: If the vascular access marked for question 21A was an AV fistula, synthetic graft or bovine graft, check all surveillance methods utilized based on the definitions and intervals given above in 21C.1. If other techniques and/or corresponding intervals were used check "other" and write in the technique and corresponding intervals.
22: Check the appropriate space to indicate if the patient FIRST started hemodialysis during January 1, 2001-August 31, 2001 (see item #8 on page 1). These patients would have begun a regular maintenance course of hemodialysis during January 1, 2001-August 31, 2001. DO NOT include patients who have changed modality, had a newly failed transplant, or returned after an episode of regained kidney function, and were placed on maintenance hemodialysis during the time frame January 1, 2001-August 31, 2001. If "Yes", answer questions 22A-B. If "No", questions 22A-B should be left blank and the form has been completed.
22A: Check the appropriate space to indicate type of vascular access in use upon Initiation of a maintenance course of hemodialysis (see item #8 on page 1) during the time frame January 1, 2001-August 31, 2001. Exclude patients who have received intermittent dialysis treatments for volume overload or congestive heart failure. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).
22B: Check the appropriate space to indicate type of vascular access, for the patient identified in 22A, in use 90 days after the patient first started hemodialysis. ("Port Access" is considered a vascular access device which consists of a valve and cannula that is subcutaneously implanted and is accessed by dialysis needles).

Appendix 3. 2002 CPM Data Collection Form – Peritoneal Dialysis

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002

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

PATIENT IDENTIFICATION <div style="border: 1px solid gray; background-color: #e0e0e0; padding: 20px; text-align: center; margin: 10px 0;"> Place Patient Data Label Here </div>	MAKE CORRECTIONS TO PATIENT INFORMATION ON LABEL IN THE SPACE BELOW
12. Patient's Ethnicity (Check appropriate box). <input type="checkbox"/> non-Hispanic <input type="checkbox"/> Hispanic, Mexican American (Chicano) <input type="checkbox"/> Hispanic, Puerto Rican <input type="checkbox"/> Hispanic, Cuban American <input type="checkbox"/> Hispanic, Other <input type="checkbox"/> Unknown	
13. If the above patient information is incorrect make corrections in space above then continue to question 12. Please verify patient's race and verify question 12 above. If patient unknown or was not dialyzed in the unit at any time during OCT 2001 – MAR 2002 return the blank form to the Network.	
14a. Patient's height (MUST COMPLETE): _____ inches OR _____ centimeters	
14b. Patient's weight (abdomen empty) (first clinic visit weight after Oct. 1, 2001): _____ lbs. OR _____ kg.	
15. Does patient have limb amputation(s): <input type="checkbox"/> Yes <input type="checkbox"/> No	
16. Has the patient ever been diagnosed with any type of diabetes? <input type="checkbox"/> Yes (go to 17) <input type="checkbox"/> No (go to 18) <input type="checkbox"/> Unknown (go to 18)	
17. If question 16 was answered YES, is the patient currently taking medications to control the diabetes? <input type="checkbox"/> Yes <input type="checkbox"/> No (go to 18) If YES, is the patient using insulin? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Individual Completing Form (Please print): First name: _____ Last name: _____ Title: _____ Phone number: (_____) _____ - _____ Fax number: (_____) _____ - _____	

INSTRUCTIONS FOR COMPLETING THE IN-CENTER PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002

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

- | | |
|--|--|
| 1. LAST and first name.
3. SOCIAL Security Number (SSN).
5. SEX (1=Male; 2=Female; 3=Unknown).
7. PRIMARY cause of renal failure by HCFA-2728 code.
9. ESRD Network number.
Do not make corrections to this item. | 2. DATE of birth (DOB) as MM/DD/YYYY.
4. HEALTH Insurance Claim Number (HIC).
6. RACE (1=American Indian/Alaska Native; 2=Asian; 3=Black; 4=White; 5=Unknown; 6=Pacific Islander; 7=Mid East Arabian; 8=Indian Subcontinent; 9=Other Multiracial).
8. DATE, as MM/DD/YYYY, that the patient began a regular course of dialysis.
10. Facility's Medicare provider number.
11. The most RECENT date this patient returned to peritoneal dialysis following: transplant failure, an episode of regained kidney function, or switched modality. |
|--|--|
12. Patient's Ethnicity. Please verify the patient's ethnicity and check appropriate box.
13. Review the patient and facility-specific information contained on the pre-printed label. Please verify the patient's race, item 6 above. If any of the information is incorrect write corrections in the space to the right of the label. If the patient is unknown or if the patient was not dialyzed in the unit at any time during OCT 2001 through MAR 2002, send the blank form back to the ESRD Network office with the name and address of the facility providing services to this patient on December 31, 2001, if known.
- 14a. Enter the patient's height in inches or centimeters. HEIGHT MUST BE ENTERED, do not leave this field blank. You may ask the patient his/her height to obtain this information. If the patient had both legs amputated, record pre-amputation height and check YES for item 15.
- 14b. Enter the patient's weight (abdomen empty) in pounds or kilograms. Use the FIRST CLINIC VISIT weight on or after October 1, 2001.
15. For the purpose of this study, check NO if this patient has had toe(s), finger(s), or mid-foot (Symes) amputation; but **check YES if this patient has had a below-knee, below-elbow, or more proximal (extensive) amputation.**
16. Check either "Yes", or "No", or "Unknown" to indicate if the patient has ever been diagnosed with any type of diabetes. If YES, proceed to question 17.
17. If the answer to 16 is YES, please check either "Yes" or "No" to indicate if the patient is currently taking medications to control the diabetes. If the answer to 17 is YES, please check either "Yes" or "No" to indicate if the patient is currently using insulin.

PLEASE COMPLETE ITEMS 18 THROUGH 24 ON PAGE 2, 3, AND 4 OF THIS DATA COLLECTION FORM.

INSTRUCTIONS FOR COMPLETING THESE ITEMS ARE ON PAGES 5 AND 6.

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)			
LAB DATA. The following data are requested for each two-month time period: OCT-NOV 2001, DEC 2001-JAN 2002, FEB-MAR 2002. For each question, where appropriate, use the first lab values obtained in each time period. ENTER THE FOLLOWING CODES IN THE SPACES BELOW IF LAB VALUES CANNOT BE LOCATED: NE if Not Found. HOSP if patient was hospitalized during the entire time period. TRANS if patient was absent during the entire time period.			
18. ANEMIA MANAGEMENT: Enter the FIRST Hemoglobin (Hgb) determined by the laboratory for EACH TWO-MONTH TIME PERIOD: OCT-NOV 2001, DEC 2001-JAN 2002, FEB-MAR 2002. Also enter the appropriate erythropoietic prescription/dose information prior to the first Hgb in each two-month time period. Enter the first monthly Serum Ferritin concentration and Transferrin Saturation, and the route of iron administration for each two-month time period.			
	OCT-NOV 2001	DEC 2001-JAN 2002	FEB-MAR 2002
A. First laboratory hemoglobin (Hgb) during the two-month time period:	_____ . _____ g/dL	_____ . _____ g/dL	_____ . _____ g/dL
B.1. Was there a prescription for Epoetin immediately before the Hgb in 18A. was drawn?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
For patients prescribed Epoetin:			
B.2. What was the PRESCRIBED Epoetin dose in units/wk at the time immediately BEFORE the Hgb in 18A. was drawn? (See instructions on page 5).	_____ units/wk	_____ units/wk	_____ units/wk
B.3. What was the prescribed route of administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC
B.4. How many times per week was Epoetin prescribed?	_____ x per week	_____ x per week	_____ x per week
C.1. Was there a prescription for Darbepoetin (Aranesp™) during the month immediately before the Hgb in 18A. was drawn?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
For patients prescribed Darbepoetin:			
C.2. What was the PRESCRIBED Darbepoetin dose in micrograms for the MONTH immediately BEFORE the Hgb in 18A. was drawn? (See instructions on page 5).	_____ mcg/month	_____ mcg/month	_____ mcg/month
C.3. How many times per month was Darbepoetin prescribed?	_____ x per month	_____ x per month	_____ x per month
C.4. What was the prescribed route of administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC	<input type="checkbox"/> IV <input type="checkbox"/> SC
D. First Serum Ferritin concentration during the two-month time period:	_____ ng/mL	_____ ng/mL	_____ ng/mL
E. First Transferrin Saturation during the two-month time period:	_____ %	_____ %	_____ %
F. Was iron prescribed at any time during the two-month time period?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19)	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to 19)
G. If yes, what was the prescribed route of iron administration? (Check all that apply).	<input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> PO	<input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> PO	<input type="checkbox"/> IV <input type="checkbox"/> IM <input type="checkbox"/> PO
H. If the patient was prescribed IV iron, what was the dose of IV iron administered during the two-month time period?	_____ mg/month	_____ mg/month	_____ mg/month
19. SERUM ALBUMIN: Enter the FIRST serum albumin FOR EACH TWO-MONTH TIME PERIOD: OCT-NOV 2001, DEC 2001-JAN 2002, FEB-MAR 2002. Check the method used (green or purple) by the lab to determine the serum albumin. If method unknown, please call lab to find out. Do not leave blank.			
	OCT-NOV 2001	DEC 2001-JAN 2002	FEB-MAR 2002
A. First serum albumin during the two-month time period:	_____ . _____ gm/dL	_____ . _____ gm/dL	_____ . _____ gm/dL
B. Check lab method used: BCG = bromcresol green; BCP = bromcresol purple	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP	<input type="checkbox"/> BCG <input type="checkbox"/> BCP
20. PERITONEAL DIALYSIS ADEQUACY: The remainder of this form lists a series of questions regarding adequacy measurements for this patient. Please answer questions 20A and B FOR EACH TWO-MONTH TIME PERIOD indicated. Then continue to pages 3 and 4.			
	OCT-NOV 2001	DEC 2001-JAN 2002	FEB-MAR 2002
A. Was the patient on peritoneal dialysis at any time during this period?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
B. Was the patient on hemodialysis or did patient receive a transplant at any time during this period?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)				
<p>21. ADEQUACY: The following data are requested for the first ADEQUACY determination during the months OCTOBER 2001 through MARCH 2002. Starting with the first adequacy measurement in these months, enter the adequacy measurements/results listed below that were obtained. (Please DO NOT record more than one adequacy measurement done for any one month.) Please read instructions on Pages 5 and 6 before completing this section.</p>		<p>22. PERITONEAL DIALYSIS PRESCRIPTION: For the following questions – record the PD prescription in effect immediately prior to the time the adequacy measures/results recorded in Question 21 were performed. In addition, if the prescription was changed following the adequacy measurement, please record the new prescription in the column indicated. Please read instructions on Page 6 before completing this section.</p>		
	<input type="checkbox"/> Check box if adequacy measurement was not done during OCT 2001-MAR 2002		Prescription prior to date in 21A	➔ New Prescription ____/____/____ (mm) (dd) (yy)
21A. Date of first adequacy measurement between 10-1-2001 to 3-31-2002	____/____/____ (mm) (dd) (yy)	22A. Number of dialysis days per week	_____ (# days)	_____ (# days)
21B. Patient's dialysis modality when adequacy measures were performed	<input type="checkbox"/> CAPD <input type="checkbox"/> Cycler	<p>22B. CAPD PRESCRIPTION (this includes patients with one overnight exchange using an assist device)</p>		
21C. Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs)	_____ lbs /kgs	1. Total dialysate volume infused per 24 hours	_____ mL/24 hrs	_____ mL/24 hrs
21D. Weekly Kt/V _{urea} (dialysate and urine clearance)	____ . ____	2. Total number of exchanges per 24 hours (including overnight exchange)	_____ (# exchanges)	_____ (# exchanges)
21E. Method by which V above was calculated: Check one. (See instructions on page 5)	<input type="checkbox"/> %BW <input type="checkbox"/> Hume <input type="checkbox"/> Watson <input type="checkbox"/> Other	<p>22C. CYCLER PRESCRIPTION</p>		
21F. Weekly Creatinine Clearance (dialysate and urine clearance)	____ . ____ L/wk	1. Total dialysate volume infused per 24 hours	_____ mL/24 hrs	_____ mL/24 hrs
21G. Is this Creatinine Clearance corrected for body surface area, using standard methods? (See instructions on page 6)	<input type="checkbox"/> Yes <input type="checkbox"/> No	2. Total dialysis time		
21H. 24 hr DIALYSATE volume (prescribed and ultrafiltration)	_____ mL	a. Total nighttime dialysis time	____hrs ____min	____hrs ____min
21I. 24 hr DIALYSATE urea nitrogen:	____ . ____ mg/dL	b. Total daytime dialysis time	____hrs ____min	____hrs ____min
21J. 24 hr DIALYSATE creatinine:	____ . ____ mg/dL	c. Total amount of time the patient is dry during 24 hours	____hrs ____min	____hrs ____min
21K. 24 hr URINE volume: (If 24 hr urine was not collected check NP. If patient's urine production was negligible, i.e., < 200 cc of urine/24 hr, then check anuric and go to question 21N)	_____ mL <input type="checkbox"/> NP <input type="checkbox"/> anuric	(Note: 2a+b+c = 24 hours)		
21L. 24 hr URINE urea nitrogen:	____ . ____ mg/dL	3. Nighttime Prescription (excluding last bag fill)		
21M. 24 hr URINE creatinine:	____ . ____ mg/dL	a. Volume of a single nighttime exchange	_____ mL/exchange	_____ mL/exchange
21N. SERUM BUN at the time this adequacy assessment was done	____ . ____ mg/dL	b. Number of dialysis exchanges during the nighttime	_____ (#/nighttime)	_____ (#/nighttime)
21O. SERUM creatinine at the time this adequacy assessment was done	____ . ____ mg/dL	4. Daytime Prescription (including last bag fill)		
21P.1. Most recent 4 hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET).	____ . ____	a. Volume of a single daytime exchange	_____ mL/exchange	_____ mL/exchange
2. Date of most recent D/P Cr	____/____/____ (mm) (dd) (yy)	b. Number of dialysis exchanges during the daytime	_____ (#/daytime)	_____ (#/daytime)
		22D. Does the prescription described above include TIDAL dialysis?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
		22E. Based on this adequacy result,		
		1. Was the collection repeated?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		2. Was the prescription changed?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
		<p>Note: If this prescription was changed, enter the new prescription date and information in the adjacent column. _____</p>		

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FOR 2002: (CONTINUED)			
<p>23. ADEQUACY: The following data are requested for the second ADEQUACY determination during the months NOVEMBER 2001 through MARCH 2002. Starting with the second adequacy measurement in these months, enter the adequacy measurements results listed below that were obtained. (Please DO NOT record more than one adequacy measurement done for any one month.) Please read instructions on Page 6 before completing this section.</p>		<p>24. PERITONEAL DIALYSIS PRESCRIPTION: For the following questions – record the PD prescription in effect immediately prior to the time the adequacy measures/results recorded in Question 23 were performed. In addition, if the prescription was changed following the adequacy measurement, please record the new prescription in the column indicated. Please read instructions on Page 6 before completing this section.</p>	
	<input type="checkbox"/> Check box if adequacy measurement was not done during NOV 2001-MAR 2002	Prescription prior to date in 23A	New Prescription ___/___/___ (mm) (dd) (yy)
23A. Date of second adequacy measurement between 11-1-2001 to 3-31-2002	___/___/___ (mm) (dd) (yy)	24A. Number of dialysis days per week _____ (# days)	_____ (# days)
23B. Patient's dialysis modality when adequacy measures were performed	<input type="checkbox"/> CAPD <input type="checkbox"/> Cyclor	24B. CAPD PRESCRIPTION (this includes patients with one overnight exchange using an assist device)	
23C. Patient's weight at the time of this adequacy assessment (abdomen empty) (Circle lbs or kgs)	_____ lbs /kgs	1. Total dialysate volume infused per 24 hours _____ mL/24 hrs	_____ mL/24 hrs
23D. Weekly Kt/V _{urea} (dialysate and urine clearance)	_____ . _____	2. Total number of exchanges per 24 hours (including overnight exchange) _____ (# exchanges)	_____ (# exchanges)
23E. Method by which V above was calculated: Check one. (See instructions on page 5)	<input type="checkbox"/> %BW <input type="checkbox"/> Hume <input type="checkbox"/> Watson <input type="checkbox"/> Other	24C. CYCLER PRESCRIPTION	
23F. Weekly Creatinine Clearance (dialysate and urine clearance)	_____ . _____ L/wk	1. Total dialysate volume infused per 24 hours _____ mL/24 hrs	_____ mL/24 hrs
23G. Is this Creatinine Clearance corrected for body surface area, using standard methods? (See instructions on page 6)	<input type="checkbox"/> Yes <input type="checkbox"/> No	2. Total dialysis time	
23H. 24 hr DIALYSATE volume (prescribed and ultrafiltration)	_____ mL	a. Total nighttime dialysis time ____ hrs ____ min	____ hrs ____ min
23I. 24 hr DIALYSATE urea nitrogen:	_____ . _____ mg/dL	b. Total daytime dialysis time ____ hrs ____ min	____ hrs ____ min
23J. 24 hr DIALYSATE creatinine:	_____ . _____ mg/dL	c. Total amount of time the patient is dry during 24 hours ____ hrs ____ min	____ hrs ____ min
23K. 24 hr URINE volume: (If 24 hr urine was not collected check NP. If patient's urine production was negligible, i.e., < 200 cc of urine/24 hr, then check anuric and go to question 23N)	_____ mL <input type="checkbox"/> NP <input type="checkbox"/> anuric	(Note: 2a+b+c = 24 hours)	
23L. 24 hr URINE urea nitrogen:	_____ . _____ mg/dL	3. Nighttime Prescription (excluding last bag fill)	
23M. 24 hr URINE creatinine:	_____ . _____ mg/dL	a. Volume of a single nighttime exchange _____ mL/exchange	_____ mL/exchange
23N. SERUM BUN at the time this adequacy assessment was done	_____ mg/dL	b. Number of dialysis exchanges during the nighttime _____ (#/nighttime)	_____ (#/nighttime)
23O. SERUM creatinine at the time this adequacy assessment was done	_____ . _____ mg/dL	4. Daytime Prescription (including last bag fill)	
23P.1. Most recent 4 hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET)	_____ . _____	a. Volume of a single daytime exchange _____ mL/exchange	_____ mL/exchange
2. Date of most recent D/P Cr	___/___/___ (mm) (dd) (yy)	b. Number of dialysis exchanges during the daytime _____ (#/daytime)	_____ (#/daytime)
		24D. Does the prescription described above include TIDAL dialysis?	<input type="checkbox"/> Yes <input type="checkbox"/> No
		24E. Based on this adequacy result,	
		1. Was the collection repeated?	<input type="checkbox"/> Yes <input type="checkbox"/> No
		2. Was the prescription changed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Note: If this prescription was changed, enter the new prescription date and information in the adjacent column. _____			

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)
INSTRUCTIONS FOR COMPLETING QUESTIONS 18 THROUGH 20 (continued from page 1): To answer questions 18 through 20 review the patient's clinic or facility medical record FOR EACH TWO-MONTH TIME PERIOD: OCT 1, 2001 through NOV 30, 2001, DEC 1, 2001 through JAN 31, 2002, and FEB 1, 2002 through MAR 31, 2002. Do not leave any items blank. Enter the following if the information cannot be located: <u>NE</u> if not found, <u>HOSP</u> if hospitalized during the entire time period, <u>TRANS</u> if patient was absent during the entire time period.
18A: Enter the patient's FIRST hemoglobin (Hgb) value determined by the laboratory for EACH two-month time period.
18B.1-B.4: Check the appropriate box to indicate if there was a prescription for Epoetin IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A was obtained. For patients prescribed Epoetin , enter the PRESCRIBED WEEKLY Epoetin DOSE at the time IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A was obtained, even if the patient did not receive the Epoetin dose (" Immediately before " refers to the week prior to the test). If prescribed less frequently than weekly, divide the prescribed Epoetin dose by the number of weeks in the dosing interval to obtain weekly Epoetin dose. If the Epoetin dose is prescribed by the number of days, divide the dose by the number of days and multiply by 7 to obtain weekly Epoetin dose (example-EPO 5000 units every 10 days. 5000 units divided by 10 days and multiplied by 7 days equals 3500 units per week). If using the sliding scale for Epoetin dosing, total all the doses given during the week and enter the value. Enter 0 units if the patient was on "hold" immediately before the hemoglobin measurement (for the purposes of this collection, a "hold" order will be considered a 0 unit prescribed dose). Enter the number of times per week that Epoetin was prescribed. Check the appropriate space to indicate the prescribed route of administration for EPO (intravenous [IV] or subcutaneous [SC]).
18C.1-C.4: Check the appropriate box to indicate if there was a prescription for Darbepoetin (Aranesp™) during the month IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A. For patients prescribed Darbepoetin , enter the PRESCRIBED DARBEPOETIN DOSE in micrograms per month (mcg/month) during the month IMMEDIATELY BEFORE the hemoglobin measurement reported in 18A, even if the patient did not receive the Darbepoetin dose. Include any prescribed dose missed due to dose skipped or error, etc., when entering the dose. Enter 0 mcg/month if the patient was on "Hold" (for the purposes of this collection, a "hold" order will be considered a 0 mcg/month prescribed dose). Enter the number of times per month that Darbepoetin was prescribed. Check the appropriate space to indicate the prescribed route of administration for Darbepoetin (intravenous [IV] or subcutaneous [SC]). If the patient received Darbepoetin IV and SC, please check both spaces.
18D: Enter the patient's FIRST serum ferritin concentration recorded EACH two-month time period. If a serum ferritin concentration test was not performed every two-month time period, enter the value for the time period when performed and record "NP" for the other time period(s).
18E: Enter the patient's FIRST transferrin saturation recorded EACH two-month time period. If a transferrin saturation test was not performed every two-month time period, enter the value for the time period when performed and record "NP" for the other time period(s).
18F: Check either "Yes" or "No" to indicate if iron was prescribed at any time during the two-month time periods.
18G: If the answer to 18F is "Yes," please check the appropriate space to indicate the route of iron administration (intravenous [IV], intramuscular [IM] or by mouth [PO]) for each two-month time period. Check every route of administration that was prescribed each time period.
18H: If the patient was prescribed IV iron, enter the dose of IV iron (in mg) that was administered during the two-month time period.
19A: Enter the patient's FIRST serum albumin value recorded EACH two-month time period.
19B: Check the method used by the laboratory to determine the serum albumin levels (bromocresol green or bromocresol purple). If you do not know what method the laboratory used, call the laboratory to find out this information. DO NOT LEAVE THIS QUESTION BLANK.
20A: Check the appropriate response (yes or no) for each two-month time period, indicating whether this patient was on peritoneal dialysis at any time during each of the specified two-month time periods.
20B: Check the appropriate response (yes or no) for each two-month time period, indicating whether this patient was on hemodialysis or received a transplant at any time during each of the specified two-month time periods.
INSTRUCTIONS FOR COMPLETING QUESTIONS 21 THROUGH 24: To answer questions 21 through 24 review the patient's clinic or facility medical record and provide the requested data for each of the first two adequacy measurements and PD prescriptions in effect immediately prior to the adequacy measurements during the months OCTOBER 2001 through MARCH 2002. DO NOT record more than one adequacy measurement done for any one month.
21A: Enter the first date on which adequacy of dialysis was assessed for the first measure obtained between OCT 1, 2001 through MAR 31, 2002. DO NOT record more than one adequacy measurement done for any one month. Check the labeled box above date area if an adequacy measurement was not done during the time frame.
21B: Check the modality of peritoneal dialysis this patient was on at the time the corresponding adequacy of dialysis measure was obtained. CHECK either CAPD or Cycler.
21C: Enter the patient's weight (with abdomen empty) at the clinic/facility visit when the adequacy measurements were obtained, circle lbs or kgs as appropriate.
21D: Enter the TOTAL WEEKLY Kt/V_{urea} for the first adequacy measurement indicated on 21A between OCT 1, 2001 through MAR 31, 2002. NOTE: If you have a value for weekly Kt/V_{urea} for this adequacy assessment, please complete the corresponding values for questions 21H-21J for 24-hour dialysate volume, 24-hour dialysate urea (or creatinine) and question 21K for 24-hour urine volume. If the patient is not anuric, complete the corresponding values for questions 21L-21M, the 24-hour urine urea (or creatinine), if these values are available. Enter NP for all values when not performed. If your unit calculates a daily Kt/V_{urea} , multiply this result by 7.0 and enter the result in the appropriate space(s). If this patient did not dialyze each day of the week, then multiply the daily Kt/V_{urea} by the number of days the patient did dialyze.
21E: Check the method used to calculate the V in the Kt/V_{urea} measurement; % BW = percent of body weight; Hume and Watson are two nomograms used to calculate V based on several of these parameters - weight, height, age, gender. If method used to calculate V is not known, please call lab to ascertain method. Please do not leave blank.

PERITONEAL DIALYSIS CLINICAL PERFORMANCE MEASURES DATA COLLECTION FORM 2002 (CONTINUED)	
21F:	Enter the TOTAL WEEKLY CREATININE CLEARANCE for the first adequacy measurement indicated on 21A between OCT 1, 2001 through MAR 31, 2002. NOTE: If you have a value for weekly creatinine clearance for this adequacy assessment, please complete the corresponding values for questions 21H-21J for 24-hour dialysate volume, 24-hour dialysate urea (or creatinine) and question 21K for 24-hour urine volume. If the patient is not anuric, complete the corresponding values for questions 21L-21M, the 24-hour urine urea (or creatinine), if these values are available. Enter NP for all values when not performed. If your unit calculates a daily creatinine clearance multiply this result by 7.0 and enter the result in the appropriate space(s). If this patient did not dialyze each day of the week, then multiply the daily creatinine clearance by the number of days the patient did dialyze.
21G:	Check Yes or No if the weekly creatinine clearance was normalized for body surface area (i.e., the result is multiplied by 1.73m ² and divided by the patient's body surface area [BSA]). Standard methods for establishing BSA are: the DuBois and DuBois method; the Gehan and George method; and the Haycock method. If you do not have this information, call the laboratory that provided the creatinine clearance value for this information. Please do not leave blank.
21H, I, and J:	Enter the measured 24-hour DIALYSATE volume (includes prescribed and ultrafiltration volumes), urea nitrogen and creatinine obtained for the first adequacy measurement obtained between OCT 1, 2001 through MAR 31, 2002. If a 24-hour dialysate volume, urea nitrogen or creatinine were NOT measured in this time period, enter NP (for not performed) in the appropriate spaces. ONLY ENTER ACTUAL MEASURED 24-HOUR DIALYSATE VOLUME. DO NOT ENTER AN EXTRAPOLATED DIALYSATE VOLUME. Please report the 24-hour dialysate volume as a combination of the prescribed fill volume and the ultrafiltration volume.
21K, L, and M:	Enter the 24-hour URINE volume, urea nitrogen and creatinine obtained for the first adequacy assessment obtained between OCT 1 2001 through MAR 31, 2002. ONLY ENTER ACTUAL MEASURED 24-HOUR URINE VOLUME—DO NOT ENTER AN EXTRAPOLATED URINE VOLUME. If 24-hour urine volume was not collected check NP for not performed, OR if the patient's urine production was negligible, i.e., < 200 cc of urine/24 hours, then check anuric. If NP or anuric is checked, SKIP TO QUESTION 21N. If urine urea nitrogen and creatinine were NOT measured in this time period, enter NP in the appropriate spaces.
21N, O:	Enter the SERUM BUN and SERUM CREATININE obtained for the first adequacy assessment obtained between OCT 1, 2001 through MAR 31, 2002. Enter NP in the appropriate spaces for all time periods when not performed.
21P:	(1) Enter the most recent four hour dialysate/plasma creatinine ratio (D/P Cr) from a peritoneal equilibration test (PET). (2) Enter the date of the most recent D/P Cr. The test result and corresponding date of the most recent D/P Cr may be outside the 6-month time frame. If never performed record "NP".
22:	To respond to questions 22A through 22E record the peritoneal dialysis (PD) prescription in effect immediately prior to the first adequacy measures/results recorded in question 21 performed between OCT 1, 2001 through MAR 31, 2002. In addition, if the prescription was changed following the adequacy measurement, please record the new prescription in the column labeled "New Prescription" as well as indicating the date that the new prescription was initiated. Complete all items that are applicable.
22A:	Enter the number of days per week for which this patient undergoes peritoneal dialysis.
22B:	CAPD PRESCRIPTION. Use the CAPD prescription category for all CAPD patients including patients with one overnight exchange using an assist device. (1) Enter the total dialysate volume in mL infused over a 24-hour period and (2) the <u>number of exchanges per 24-hour period</u> PRESCRIBED for CAPD at the time the first adequacy measurements were performed.
22C:	CYCLER PRESCRIPTION. (1) Enter the total dialysate volume in mL infused over a 24-hour period. (2) Total dialysis time - (Note: 2a+b+c = 24 hours): (2a) Enter the total nighttime dialysis time, (2b) the total daytime dialysis dwell time, and (2c) the <u>total amount of time the patient is dry during 24 hours</u> . If the patient is never dry in 24 hours enter a value of 0 hours. The hours entered in 2a, b, & c should equal 24 hours. (3) Nighttime Prescription (excluding last bag fill): (3a) Enter <u>the volume of a single nighttime exchange</u> and (3b) the <u>number of dialysis exchanges during the nighttime</u> PRESCRIBED for CYCLER NIGHTTIME at the time the first adequacy measurements were performed. Include in the CYCLER NIGHTTIME prescription only those exchanges provided by an automated device. DO NOT include in this category any last bag fill or option that the patient carries after unhooking from the cyclor or any daytime dwells as these exchanges are recorded in the DAYTIME PRESCRIPTION information. If different inflow volumes are used, report average inflow volume. (4) Daytime Prescription (including last bag fill): (4a) Enter <u>the volume of a single daytime exchange</u> and (4b) the <u>number of dialysis exchanges during the daytime</u> PRESCRIBED for CYCLER DAYTIME at the time the first adequacy measurements were performed. Include in the CYCLER DAYTIME prescription only those exchanges performed after the patient disconnects from the cyclor and/or a last bag fill or option that the patient carries during the day. ANY OTHER EXCHANGES PERFORMED USING THE CYCLER SHOULD BE INCLUDED UNDER CYCLER NIGHTTIME PRESCRIPTION. If different inflow volumes are used, report average inflow volume.
22D:	Check the appropriate box, yes or no, whether this patient's peritoneal dialysis prescription included TIDAL dialysis. TIDAL patients are cyclor patients for whom the dialysate is partially drained between some exchanges.
22E:	(1) Check the appropriate box, yes or no, indicating whether the adequacy collection was repeated, or the prescription changed, following the first adequacy measurement performed between OCT 1, 2001 through MAR 31, 2002. (2) If the prescription was changed enter the new prescription in the column to the right.
23A-P:	See instructions for 21A-21P and complete for second adequacy measurement performed between NOV 1, 2001 through MAR 31, 2002. DO NOT record more than one adequacy measurement done for any one month. Check the labeled box above date area if an adequacy measurement was not done during the time frame.
24A-E:	See instructions for 22A-22E and complete for the peritoneal dialysis (PD) prescription in effect immediately prior to the second adequacy measures/results recorded in question 23 performed between NOV 1, 2001 through MAR 31, 2002.

Appendix 4. 2002 CPM Facility-Specific Data Collection Form**DIALYSIS FACILITY CLINICAL PERFORMANCE
MEASURES DATA COLLECTION FORM 2002**

FACILITY IDENTIFICATION

MAKE CORRECTIONS TO FACILITY INFORMATION
ON LEFT IN THE SPACE BELOW

Place Facility Label Here

1. Does your facility have a written policy for the **TIMING** of the post-dialysis BUN sample collection? (*This question refers to any written policy, endorsed by your facility's management and to which adherence is expected, regarding the timing of blood draws for the assessment of post-dialysis BUN samples.*)

Yes No

If yes, which of the following would best describe your facility's written policy for the **TIMING** of the post-dialysis BUN sample collection as of October 1, 2001? [**CHECK ONLY ONE ANSWER**]

- | | |
|---|---|
| <input type="checkbox"/> Immediately, without slowing blood flow | <input type="checkbox"/> Immediately after slowing or stopping blood flow |
| <input type="checkbox"/> 15 to 60 seconds after slowing or stopping blood flow | <input type="checkbox"/> 61 to 120 seconds after slowing or stopping blood flow |
| <input type="checkbox"/> > 2 to 15 minutes after slowing or stopping blood flow | <input type="checkbox"/> > 15 minutes after slowing or stopping blood flow |

2. During the time period January 1, 2001 to December 31, 2001, did your facility conduct and document an audit of adherence to the written policy for post-dialysis BUN sample collection? (*An audit refers to an actual physical observation and verification of post-dialysis BUN blood sample draws in order to assess compliance with the policy identified in question 1.*)

Yes No Unknown

3. During the time period October 1, 2001 to December 31, 2001 did your facility re-process (re-use) dialyzers? (*Please answer "Yes" if your facility re-used one or more dialyzer(s) between October 1, 2001 and December 31, 2001.*)

Yes No Unknown

If yes, please check the box(es) which most accurately represents the proportion of reprocessed dialyzers for which total cell volume (TCV) is measured in your facility prior to first use: [**CHECK ALL THAT APPLY**]

- < 95 % 95 - 100 %
- We use the dialyzer manufacturer's product information to infer TCV
- We use batch testing and/or an average TCV for a group of hemodialyzers to infer TCV
- Other _____

Individual Completing Form (**Please print**):

First name: _____ Last name: _____ Title: _____

Phone number: (____) _____ - _____ Fax number (____) _____ - _____

Appendix 5. Centers for Medicare & Medicaid Services (CMS) Offices and ESRD Networks

CMS Offices

Centers for Medicare & Medicaid Services
Center for Beneficiary Choices
Quality Measurement and Health Assessment
Group
S3-02-01
7500 Security Boulevard
Baltimore, MD 21244
(410) 786-5785

Centers for Medicare & Medicaid Services -
Region I
Division of Clinical Standards and Quality,
Clinical Standards Branch
Room 2275
JFK Federal Building
Boston, MA 02203-0003
(617) 565-3136

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

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

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

ESRD Networks

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

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

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

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

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

ESRD Network Organization No. 6
Southeastern Kidney Council, Inc.
1000 St. Albans Drive
Suite 270
Raleigh, NC 27609
Region VI: GA, NC, SC
(919) 855-0882

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

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

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

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

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

ESRD Network Organization No. 13
6600 N Meridan Ave, Ste 155
Oklahoma City, OK 73116-1411
Region VI: AR, LA, OK
(405) 843-8688

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

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

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

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

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

Appendix 6. ESRD CPM Quality Improvement Committee Members

Kenneth Abreo, MD
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Lawrence Agodoa, MD +
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Baltimore, MD 21287-2535

Bradley Warady, MD +
Kansas, City, MO 64108

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^ Peritoneal Dialysis Subcommittee Member

* Vascular Access Subcommittee Member

+ Pediatric Subcommittee Member

Appendix 7. List of Publications/Abstracts/Supplemental Reports of ESRD CPM and Core Indicators Data

Publications

1. McClellan WM, Frederick P, Helgerson S, Hayes R, Ballard D, McMullan M. A Health Care Quality Improvement Program for End-Stage Renal Disease (ESRD). *Health Care Financing Review* 1995; 16:129-140.
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4. Prowant BF, Taylor L, Frederick PR. Health Care Financing Administration (HCFA) 1995 Core Indicators for Peritoneal Dialysis. *ANNA Journal* 1997;24:196.
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18. Frankenfield DL, Eggers PW, Greer JW, Rocco MV, Frederick PR, Owen WF. Comparison of Intermediate Outcomes for Fee-For-Service and HMO In-Center Hemodialysis Patients: Results from the 1998 ESRD Core Indicators Project. *J Am Soc Nephrol* 1910(September):163A.
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Supplemental Reports**1994***Supplemental Report #1*

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

Supplemental Report #2

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

Supplemental Report #3

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

Special Populations Report

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

1995*Supplemental Report # 1*

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

Special Populations Report

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

1996*Special Report #A*

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

Special Report #B

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

Supplemental Report #1

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

Supplemental Report #2

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

Supplemental Report #3

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

Supplemental Report #4

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

1997*Special Report #A*

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

Supplemental Report #1

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

Supplemental Report #2

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

Supplemental Report #3

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

1998*Special Report #A*

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

Supplemental Report #1

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

Supplemental Report #2

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

1999*Supplemental Report #1*

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

Supplemental Reports (continued)

Supplemental Report #2

Network trends, 1993-1999 (July 2000)

2000

Supplemental Report #1

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

Supplemental Report #2

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

Supplemental Report #3

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

2001

Supplemental Report #1

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

Supplemental Report #2

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

Supplemental Report #4

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

Supplemental Report #5

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

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

**2002 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
# in sample	454	466	419	455	482	488	483	480	472	442	470	434	480	486	470	468	467	483	8399
Dialysis Adequacy	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
% Pts with Mean Kt/V ≥ 1.2	91	86	88	90	88	89	87	89	89	88	87	89	86	92	91	88	86	89	89
Median Kt/V	1.49	1.47	1.45	1.52	1.49	1.48	1.47	1.48	1.50	1.47	1.47	1.49	1.48	1.58	1.55	1.55	1.48	1.48	1.49
% Pts with Mean URR ≥ 65%	87	84	82	87	84	84	83	84	85	83	84	83	81	89	87	85	82	84	84
Median URR %	71.7	71.1	70.9	72.2	71.5	71.0	70.9	71.2	71.7	71.0	71.0	71.8	71.0	73.2	72.3	72.8	71.5	71.3	71.5
Median Blood Pump Flow (mL/min)	400	400	400	400	400	400	400	417	400	400	400	405	400	400	400	400	400	400	400
Median Dialysis Session Length (min)	210	210	213	225	210	219	210	225	225	220	210	212	218	235	210	235	195	205	212
Vascular Access	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
% Prevalent Pts with AVF	46	38	32	28	25	28	29	29	28	32	29	35	24	23	35	45	33	35	31
% Incident Pts with AVF	45	32	33	27	27	23	22	30	25	28	27	30	13	22	29	49	33	35	29
% Prevalent Pts with AVG	29	39	32	43	46	45	39	50	39	41	44	39	49	57	40	36	50	45	43
% pts with AVG and stenosis monitoring	28	57	54	48	44	25	49	68	59	67	55	60	43	62	39	61	71	36	51
% Prevalent Pts with catheter	25	22	36	29	28	27	32	21	33	27	27	27	27	20	25	19	17	20	26
% Prevalent Pts with catheter ≥ 90 days	17	15	30	24	20	22	26	16	26	21	19	21	22	15	18	13	13	15	19

2002 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients

Anemia Mgement	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
Median Hgb	11.6	11.7	11.8	11.7	11.9	11.8	11.7	11.6	11.7	11.9	11.7	11.6	11.6	11.7	11.9	11.9	11.8	11.7	11.7
% Pts with Mean Hgb ≥ 11gm/dL	76	75	78	77	77	76	78	73	74	76	76	75	73	76	81	78	76	77	76
% Pts with Mean Hgb 11-12.0 gm/dL*	45	38	39	43	35	36	40	41	32	34	41	42	39	38	38	33	35	42	38
% Pts with Mean Hgb < 10gm/dL	7	7	10	6	7	9	8	11	8	9	10	9	9	8	7	5	7	7	8
Median wkly IV EPO dose units/kg/wk	201.9	210.8	235.9	200.6	204.5	219.3	171.0	201.5	209.5	220.1	189.3	186.8	196.5	187.3	167.3	176.7	181.7	205.9	199.1
Median wkly SCEPO dose units/kg/wk	172.7	194.1	158.0	166.2	139.1	165.4	248.8	160.0	185.2	217.4	157.6	149.7	130.3	155.7	301.7	107.1	165.9	161.9	167.2
% Pts Rx'd^ SCEPO	7	4	12	3	4	3	4	5	19	13	11	18	9	15	*	14	15	19	10
Iron Mgement	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
% Pts with Mean TSAT ≥ 20%	78	81	82	79	83	85	86	78	77	79	79	74	79	79	77	70	75	85	80
Median TSAT %	26.0	28.0	27.0	27.0	27.7	28.3	28.3	26.7	25.0	26.0	27.2	24.7	26.3	26.3	25.7	25.0	25.7	28.0	26.7
% Pts with Mean Ferritin ≥ 100 ng/mL	89	87	91	90	90	92	94	93	95	93	93	91	92	92	90	89	90	93	92
Median Ferritin ng/mL	436	489	485	512	465	567	657	554	591	633	547	481	603	513	468	467	510	568	533
% Pts Rx'd IV Iron	62	63	64	65	59	60	65	61	70	68	68	62	60	65	63	69	62	60	64

^ Among those patients prescribed Epoetin

* Value suppressed because n ≤ 10

**2002 NATIONAL CPM DATA COLLECTION – NATIONAL AND NETWORK PROFILES (cont.)
for Adult (aged ≥ 18 years) In-Center Hemodialysis Patients**

Albumin	Net 1	Net 2	Net 3	Net 4	Net 5	Net 6	Net 7	Net 8	Net 9	Net 10	Net 11	Net 12	Net 13	Net 14	Net 15	Net 16	Net 17	Net 18	US
% Pts with Mean serum albumin ≥ 4.0/3.7 gm/dL	32	37	33	34	42	38	35	36	31	36	34	31	38	39	33	27	35	43	36
% Pts with Mean serum albumin ≥ 3.5/3.2 gm/dL	80	80	80	83	83	83	83	83	82	84	77	79	86	82	81	73	85	84	82
Median serum BCG albumin (gm/dL)	3.8	3.9	3.8	3.8	3.9	3.8	3.9	3.8	3.8	3.9	3.8	3.8	3.9	3.9	3.8	3.8	3.8	3.9	3.8
Median serum BCP albumin (gm/dL)	3.5	3.5	3.5	3.5	3.8	3.9	3.8	3.7	3.6	3.8	3.6	3.6	3.8	3.7	3.5	3.3	3.6	3.6	3.6

Appendix 9. 2002 ESRD CPM Outcome Comparison Tool – Adult In-Center Hemodialysis Patients – National and Network Data are from October – December 2001.

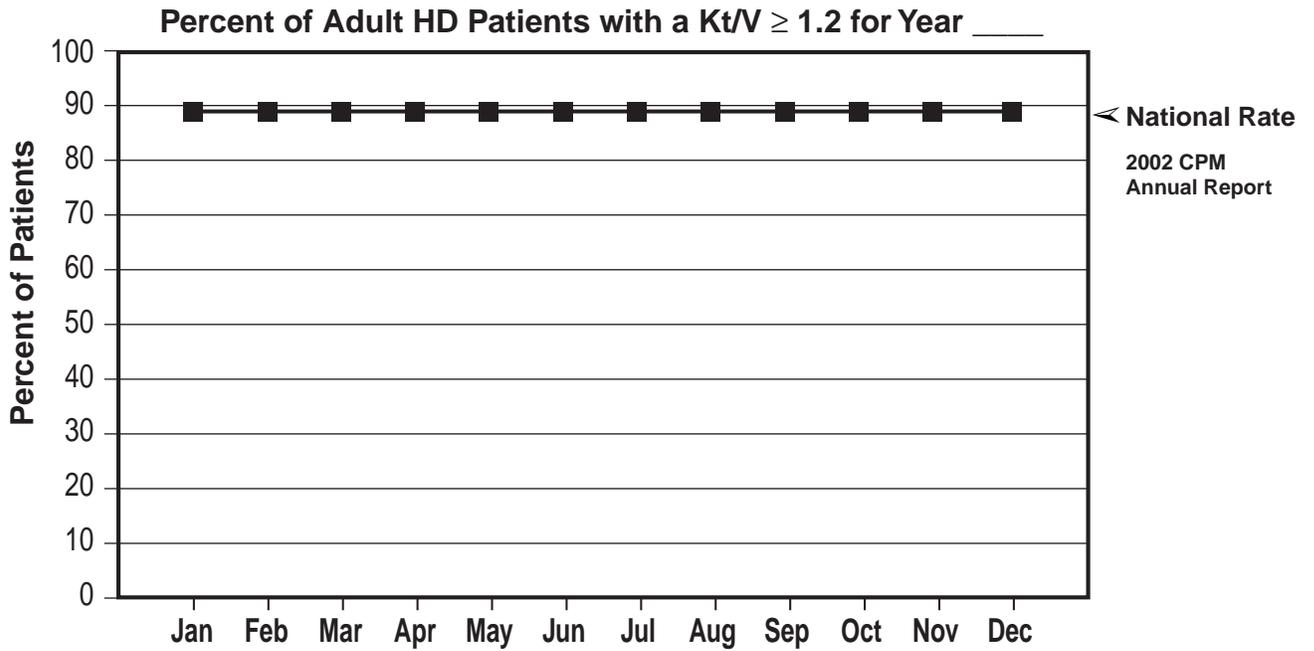
Enter your Network data from Appendix 8 and use this tool to document and compare your facility outcomes to the national data and your Network data.

	US	Network	Facility
Adequacy of Dialysis			
Percent of patients with a mean Kt/V \geq 1.2	89%		
Median Kt/V	1.49		
Median blood pump flow rate (mL/minute)	400		
Median dialysis session length (minutes)	212		
Vascular Access			
Percent of prevalent patients dialyzed with an AVF	31%		
Percent of incident patients dialyzed with an AVF	29%		
Percent of prevalent patients dialyzed with an AV graft	43%		
Percent of prevalent patients dialyzed with a catheter	26%		
Percent of prevalent patients dialyzed with a catheter \geq 90 days	19%		
Anemia Management			
Percent of patients with mean Hgb \geq 11.0 gm/dL	76%		
Percent of targeted [†] patients with mean Hgb 11.0 – 12.0 gm/dL	38%		
Percent of patients with mean Hgb < 10.0 gm/dL	8%		
Median Hgb (gm/dL)	11.7		
Median weekly Epoetin dose (units/kg/week)			
IV	199.1		
SC	167.2		
Percent of patients* prescribed SC Epoetin	10%		
Percent of patients with mean TSAT \geq 20%	80%		
Median TSAT (%)	26.7		
Percent of patients with mean serum ferritin concentration \geq 100 ng/mL	92%		
Median serum ferritin concentration (ng/mL)	533		
Percent of patients prescribed IV iron	64%		
Serum Albumin			
Percent of patients with mean serum albumin \geq 4.0/3.7 gm/dL (BCG/BCP)	36%		
Percent of patients with mean serum albumin \geq 3.5/3.2 gm/dL (BCG/BCP)	82%		
Median serum albumin (gm/dL)			
BCG	3.8		
BCP	3.6		

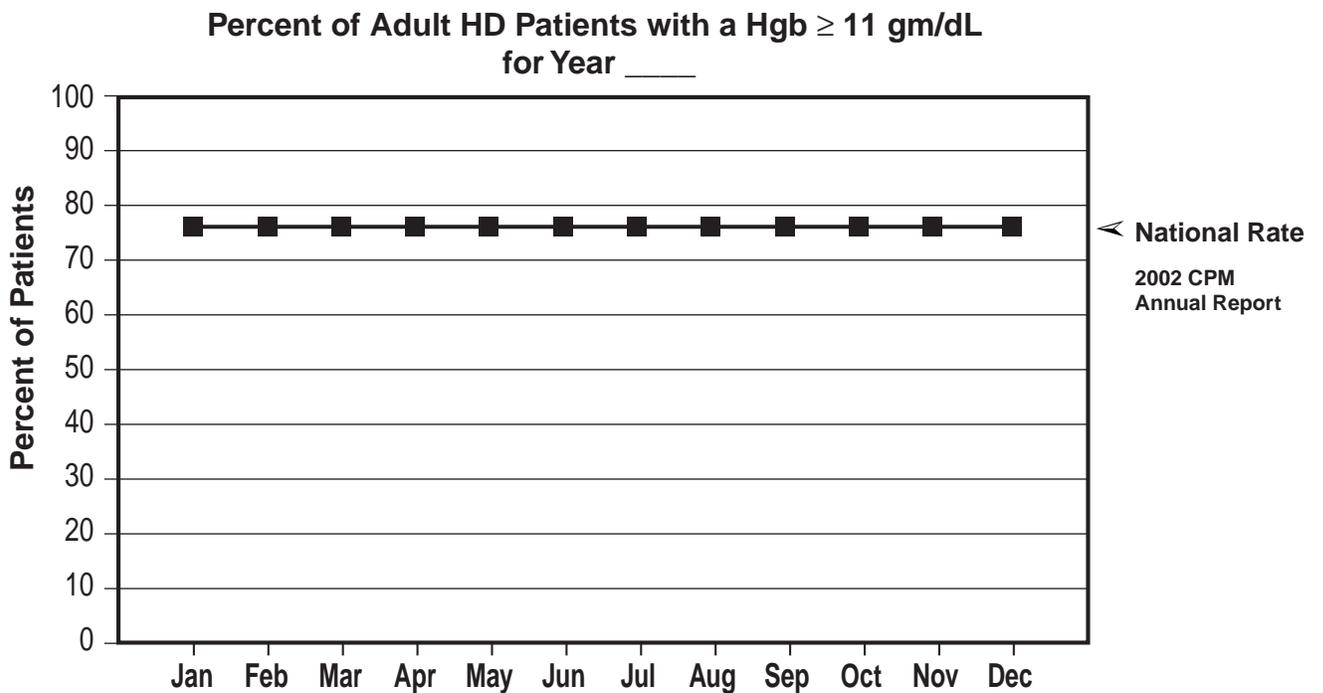
[†] See appendix 1 for complete definition of targeted patients for this CPM.

* Among those patients prescribed Epoetin.

Use the following chart to plot monthly the percent of adult HD patients in your unit that have a Kt/V ≥ 1.2 (Nation = 89%). Post the chart in the facility for all to see.



Use the following chart to plot monthly the percent of adult HD patients in your unit that have a Hgb ≥ 11 gm/dL (Nation = 76%). Post the chart in the facility for all to see.



CUT ALONG THIS LINE

Appendix 10. 2002 ESRD CPM Outcome Comparison Tool – Adult Peritoneal Dialysis Patients – National Data are from October 2001 – March 2002.

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

	US	Facility
Adequacy of Dialysis		
Percent of patients measured for adequacy at least once during the six month study period (both weekly Kt/V_{urea} and weekly creatinine clearance measured)	86%	
Percent of CAPD patients with mean weekly $Kt/V_{urea} \geq 2.0$	72%	
Median weekly Kt/V_{urea} for CAPD patients	2.27	
Percent of Cycler patients with a daytime dwell with mean weekly $Kt/V_{urea} \geq 2.1$	66%	
Median weekly Kt/V_{urea} for Cycler patients with a daytime dwell	2.25	
Percent of Cycler patients without a daytime dwell with mean weekly $Kt/V_{urea} \geq 2.2$	61%	
Median weekly Kt/V_{urea} for Cycler patients without a daytime dwell	2.29	
Anemia Management		
Percent of patients with mean Hgb ≥ 11.0 gm/dL	76%	
Percent of targeted [†] patients with mean Hgb 11.0 – 12.0 gm/dL	36%	
Percent of patients with mean Hgb < 10.0 gm/dL	8%	
Median Hgb (gm/dL)	11.8	
Percent of patients* prescribed SC Epoetin	98%	
Percent of patients with mean TSAT $\geq 20\%$	83%	
Median TSAT (%)	27.4	
Percent of patients with mean serum ferritin ≥ 100 ng/mL	84%	
Median serum ferritin concentration (ng/mL)	287	
Percent of patients prescribed IV iron	20%	
Serum Albumin		
Percent of patients with mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP)	19%	
Percent of patients with mean serum albumin $\geq 3.5/3.2$ gm/dL (BCG/BCP)	61%	
Median serum albumin (gm/dL)		
BCG	3.6	
BCP	3.3	

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

* Among those patients prescribed Epoetin.

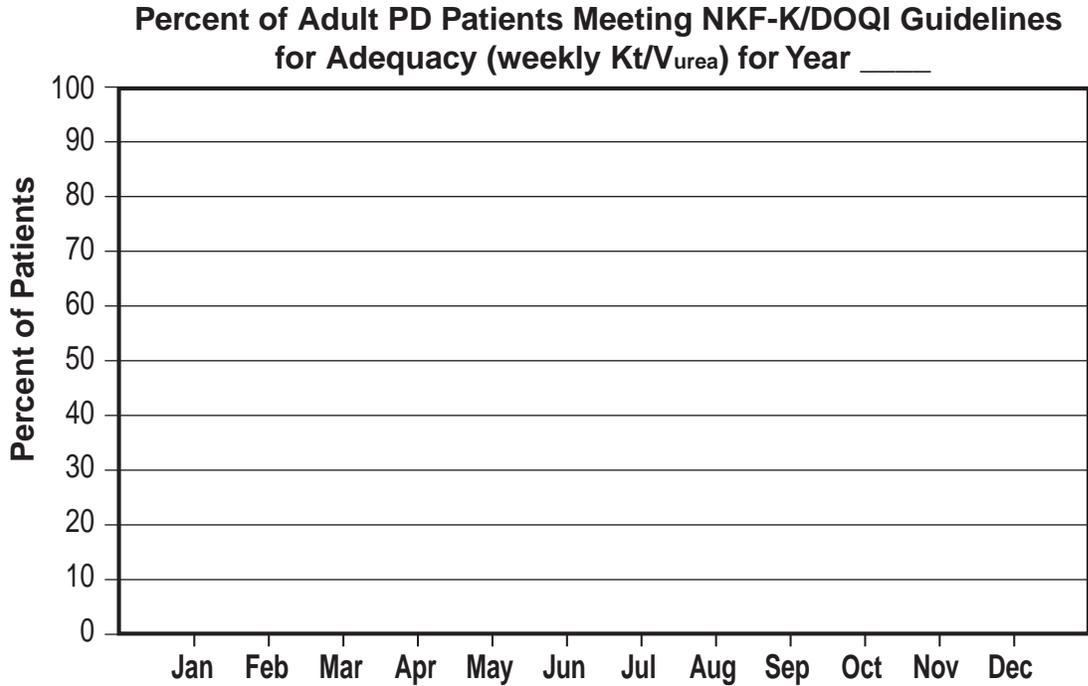
Use the following chart to plot monthly:

The % of adult CAPD patients in your unit that have a $Kt/V_{urea} \geq 2.0$ (Nation = 72%).

The % of adult Cycler patients with a daytime dwell that have a $Kt/V_{urea} \geq 2.1$ (Nation = 66%);

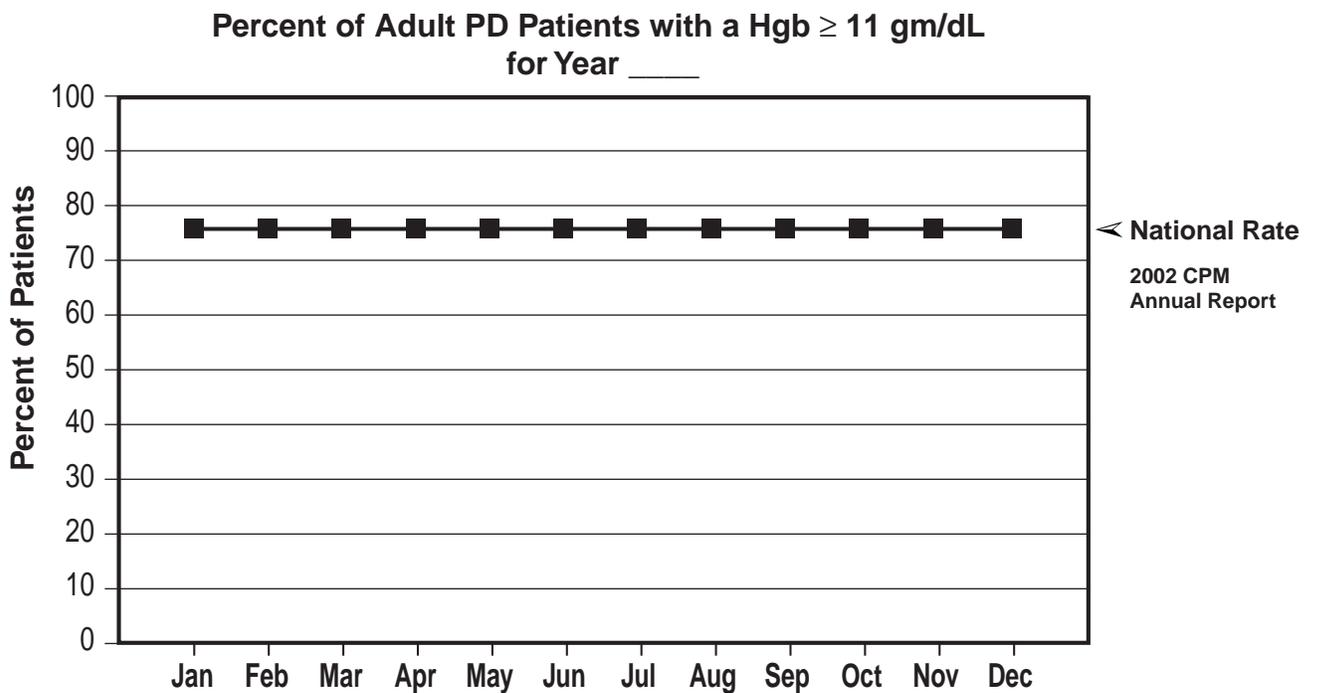
The % of adult Cycler patients without a daytime dwell that have a $Kt/V_{urea} \geq 2.2$ (Nation = 61%).

Post the chart in the facility for all to see.



CUT ALONG THIS LINE

Use the following chart to plot monthly the percent of adult PD patients in your unit that have a Hgb ≥ 11 gm/dL (Nation = 76%).
Post the chart in the facility for all to see.



NOTES

NOTES