



December 31, 2000

7500 SECURITY BOULEVARD  
BALTIMORE MD 21244-1850

Dear Dialysis Provider:

The Health Care Financing Administration (HCFA) and the End Stage Renal Disease (ESRD) Network Organizations are pleased to provide you with a copy of the 2000 Annual Report of the ESRD Clinical Performance Measures Project, formerly known as the ESRD Core Indicators Project. This report provides results of several clinical performance measures (CPMs) of importance for adult in-center hemodialysis and adult peritoneal dialysis patients. The clinical data collected for this report are from October 1999–December 1999 for the hemodialysis patients and October 1999–March 2000 for the peritoneal dialysis patients. These CPMs include measures of adequacy of dialysis, anemia management and vascular access. The report also provides a comparison of several clinical measures or indicators from the last quarters of 1994, 1995, 1996, 1997, 1998, and 1999 for all 18 ESRD Network areas. The data collected for this project by more than 2,000 dialysis facilities such as yours have made this report possible.

Please review the information in this report and examine your own care processes.

*What percentage of hemodialysis patients and peritoneal dialysis patients at your facility are receiving adequate dialysis? What percentage of your hemodialysis patients are dialyzed using an arterial venous fistula or a catheter? What percentage of your patients have hemoglobins  $\geq 11$ ? How do these measures or indicators of care for the patients in your facility compare to national and/or Network levels? What improvements have been achieved at your facility since the end of 1999?*

The information in this report should stimulate you to ask and answer questions such as these and, where indicated, to develop ways to improve care for your patients. Your ESRD Network is available to assist you in developing and implementing improvement strategies.

This report, as well as previous reports, is available on the Internet at

[www.hcfa.gov/quality/3m.htm](http://www.hcfa.gov/quality/3m.htm)

Also available on this website is a Power Point file containing the figures from this report. We ask that you take the time to review these reports and provide us with feedback as to their usefulness and ways you would like to see the clinical information displayed. We believe that by working together we will serve our mutual interest of improving the quality of care for dialysis patients. Finally, please take the time to visit “Dialysis Facility Compare” at [www.medicare.gov](http://www.medicare.gov). This is our latest initiative to be implemented in early 2001 that provides dialysis facility-specific information to the public. We would like to thank the renal community for their support and assistance in making this new website a reality.

Sincerely,

A handwritten signature in cursive script that reads "Jeffrey L. Kang".

Jeffrey L. Kang, MD, MPH

Director

Office of Clinical Standards and Quality

Enclosure

**2000 ANNUAL REPORT  
ESRD CLINICAL PERFORMANCE  
MEASURES PROJECT  
(Formerly ESRD Core Indicators Project)**

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

**DECEMBER 2000**



Department of Health and Human Services  
Health Care Financing Administration  
Office of Clinical Standards and Quality  
Baltimore, Maryland



Data on in-center hemodialysis patients are from October–December 1999

Data on peritoneal dialysis patients are from October 1999–March 2000

Suggested citation for this report is as follows:

Health Care Financing Administration. 2000 Annual Report, End Stage Renal Disease Clinical Performance Measures Project. Department of Health and Human Services, Health Care Financing Administration, Office of Clinical Standards and Quality, Baltimore, Maryland, December 2000.

Note: The clinical data collected for the 2000 ESRD Clinical Performance Measures Project were from the time period of October–December 1999 for the in-center hemodialysis patients and the time period of October 1999–March 2000 for the peritoneal dialysis patients.

#### **2001 Data Collection Effort**

In 2001, we will again collect data for the ESRD Clinical Performance Measures on a national sample of adult in-center hemodialysis and adult peritoneal dialysis patients.

Any questions about the Project may be addressed to your ESRD Network staff or to members of the ESRD Clinical Performance Measures Quality Improvement Workgroup (APPENDICES 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.hcfa.gov/quality/3m.htm](http://www.hcfa.gov/quality/3m.htm)

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## ACKNOWLEDGMENTS

The Health Care Financing Administration (HCFA) wishes to acknowledge the following groups and persons without whose efforts this report would not have been possible:

- The members of the End-Stage Renal Disease (ESRD) Clinical Performance Measures (CPM) Quality Improvement (QI) Committee and the members of the Peritoneal Dialysis and the Vascular Access Subcommittees (See Appendix 6).
- The eighteen ESRD Network Organizations throughout the United States (See Appendix 5).
- The following HCFA Central Office staff: Diane L. Frankenfield, DrPH, Ava Marie Chandler, and Debbie Grossblatt.
- 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 2,500 dialysis facilities in the United States who abstracted the requested information from medical records on more than 8,000 adult in-center hemodialysis and peritoneal dialysis patients.
- The many other individuals in the renal community and HCFA who contributed to this work.

## ACRONYMS

### List of Commonly Used Acronyms

**AVF** Arterial Venous Fistula

**BSA** Body Surface Area

**BUN** Blood Urea Nitrogen

**CAPD** Continuous Ambulatory Peritoneal Dialysis

**CCPD** Continuous Cycling Peritoneal Dialysis

**CIP** Core Indicators Project

**CPM** Clinical Performance Measure

**CQI** Continuous Quality Improvement

**CrCl** Creatinine Clearance

**DOQI** Dialysis Outcomes Quality Initiative

**ESRD** End-Stage Renal Disease

**GFR** Glomerular Filtration Rate

**HCFA** Health Care Financing Administration

**HCQIP** Health Care Quality Improvement Program

**HD** Hemodialysis

**Hgb** Hemoglobin

**IV** Intravenous

**Kt / V or Kt / V<sub>urea</sub>** Urea Clearance x Time normalized by total body water/the Volume of distribution of Urea

**NIPD** Nightly Intermittent Peritoneal Dialysis

**NKF** National Kidney Foundation

**PD** Peritoneal Dialysis

**QA** Quality Assurance

**QI** Quality Improvement

**RRF** Residual Renal Function

**SC** Subcutaneous

**SD** Standard Deviation

**TCV** Total Cell Volume

**UKM** Urea Kinetic Modeling

**URR** Urea Reduction Ratio

**USRDS** United States Renal Data System

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## I. EXECUTIVE SUMMARY

The ESRD Clinical Performance Measures (CPM) Project<sup>1</sup>, now in its seventh year, is a national effort led by HCFA and its eighteen ESRD Networks to assist dialysis providers in the improvement of patient care and outcomes. Since 1994 the project has documented continued improvements in dialysis patient care and outcomes, 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 2000 ESRD CPM Annual Report once again describes the findings of several important clinical measures and/or characteristics of a nationally representative random sample of adult (aged  $\geq 18$  years) in-center hemodialysis patients (during October-December 1999) and peritoneal dialysis patients (during October 1999-March 2000) in the US. This report also compares the 2000 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.hcfa.gov/quality/3m.htm](http://www.hcfa.gov/quality/3m.htm). A Power Point file 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.

The 2000 ESRD CPM Annual Report is formatted somewhat differently than previous reports. It contains three major sections: Background and Project Methods, In-Center Hemodialysis Patients, Peritoneal Dialysis Patients, References, and several appendices.

The **Background and Project Methods** section, beginning on page 14, 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.

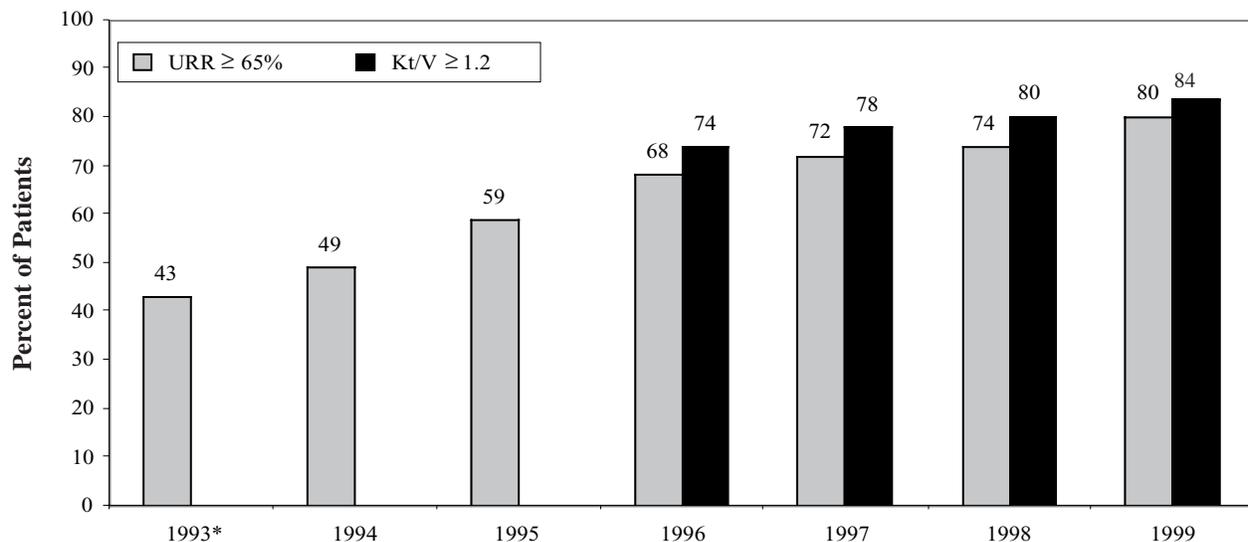
The following are highlights from the **In-Center Hemodialysis Patient** section (pages 20-41):

- 84% of the patients in late 1999 received dialysis with a delivered Kt/V  $\geq 1.2$ , an increase from 80% at the end of 1998 (FIGURE 2).
- Approximately 23,000 more patients received dialysis with a Kt/V  $\geq 1.2$  in late 1999 than would have received dialysis at this level in late 1996 (FIGURES 2, 3).
- 68% of the patients in late 1999 had a mean hemoglobin  $\geq 11$  gm/dL, an increase from 59% in late 1998 (FIGURE 4).
- The mean hemoglobin for these patients increased from 11.1 gm/dL in late 1998 to 11.4 gm/dL in late 1999 (FIGURE 5).
- 60% of patients prescribed Epoetin had a mean hemoglobin of 11-12.9 gm/dL during October-December 1999 (TABLE 11).
- 80% of patients had a mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP laboratory methods); 32% of patients had a mean serum albumin  $\geq 4.0/3.7$  gm/dL (BCG/BCP) during October-December 1999 (FIGURE 33).

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<sup>1</sup> In 1999 the ESRD Core Indicators project and the ESRD Clinical Performance Measures (CPM) Project were merged. The project is now known as the ESRD CPM Project.

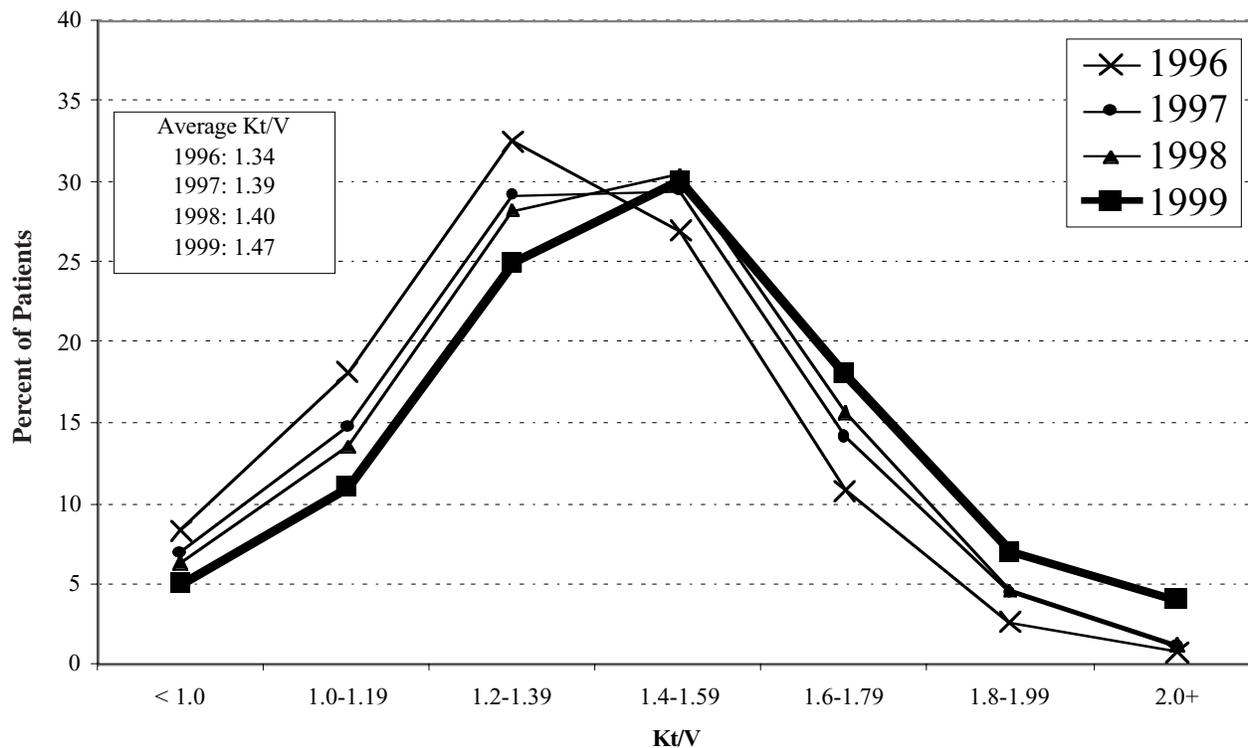
**Figure 2:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean URR  $\geq 65\%$  in October–December 1999, compared to October–December 1993, 1994, 1995, 1996, 1997, and 1998 and percent of patients with mean Kt/V  $\geq 1.2$ , October–December 1999 compared to October–December 1996, 1997, and 1998. 2000 ESRD CPM Project.



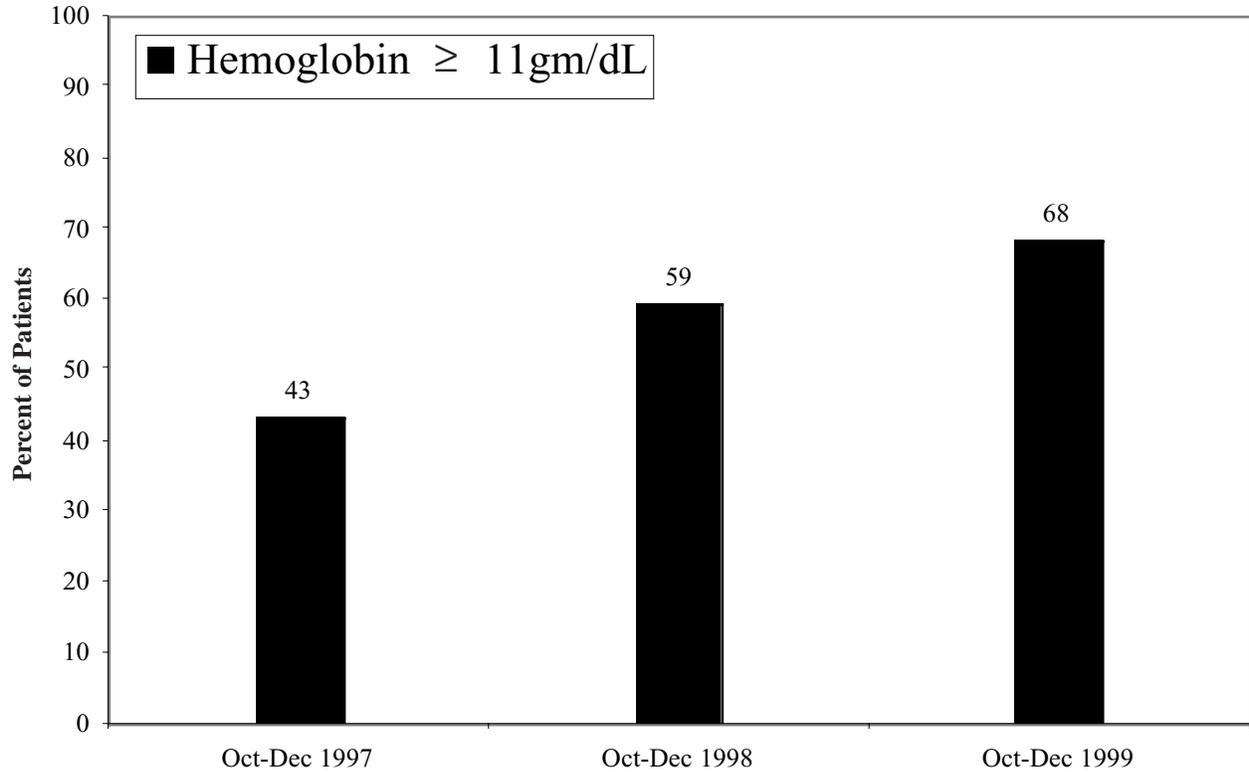
\*Sixteen Network areas participated in the first ESRD Core Indicators assessment (October–December 1993); all Network areas participated in subsequent years.

\*\*Information to calculate Kt/V was not collected until 1996.

**Figure 3:** Distribution of mean Kt/V values for adult (aged  $\geq 18$  years) in-center hemodialysis patients, October–December 1999 compared to October–December 1996, 1997, and 1998. 2000 ESRD CPM Project.

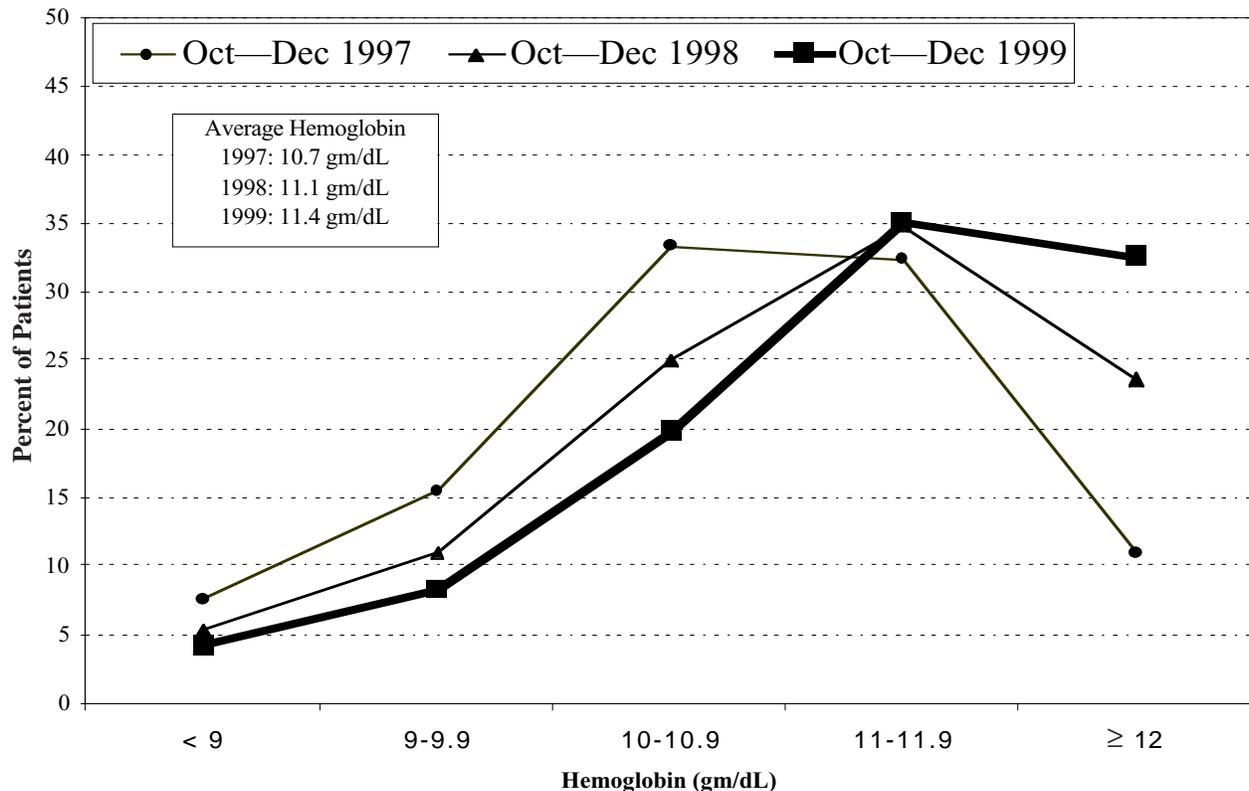


**Figure 4:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean hemoglobin  $\geq 11$  gm/dL, October–December 1999 compared to October–December 1997 and 1998. 2000 ESRD CPM Project.



The relationship between hematocrit and hemoglobin differs significantly depending upon the instrumentation used to measure them and therefore are not comparable. (1)

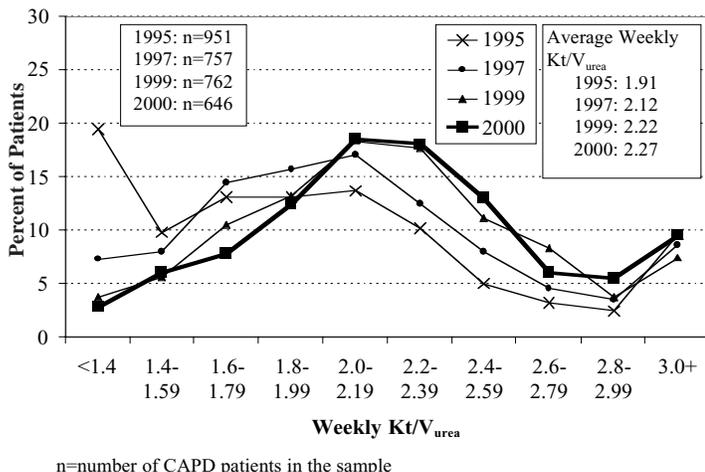
**Figure 5:** Distribution of mean hemoglobin values for adult (aged  $\geq 18$  years) in-center hemodialysis patients, October–December 1999 compared to October–December 1997 and 1998. 2000 ESRD CPM Project.



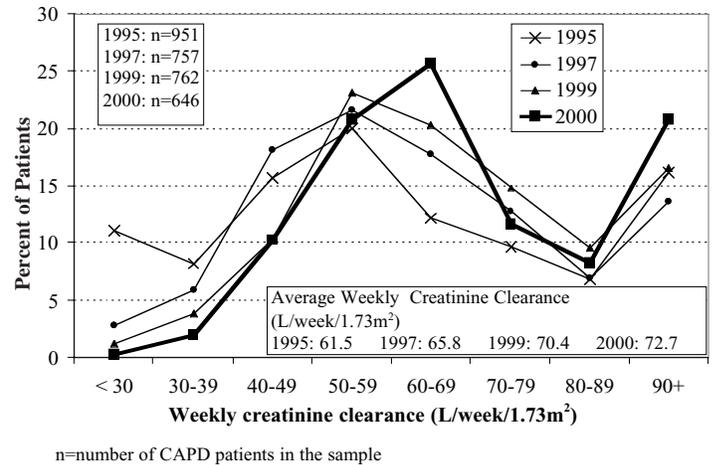
The following are highlights from the **Peritoneal Dialysis Patient** section (pages 42-49):

- Adequacy of dialysis was assessed at least once for approximately 85% of the patients sampled during the 2000 study period (FIGURE 34).
- 65% of CAPD patients met an adequate weekly Kt/V<sub>urea</sub> and 61% met an adequate weekly CrCl according to NKF-DOQI guidelines (TABLE 16).
- 60% of cycler patients met an adequate weekly Kt/V<sub>urea</sub> and 51% met an adequate weekly CrCl according to NKF-DOQI guidelines (TABLE 16).
- For CAPD patients, the mean weekly Kt/V<sub>urea</sub> increased from 2.22 to 2.27, and the mean weekly creatinine clearance increased from 70.4 to 72.7 L/week/1.73m<sup>2</sup> from study period 1999 to study period 2000 (FIGURES 6, 7, TABLE 16).
- For cycler patients, the mean weekly Kt/V<sub>urea</sub> increased from 2.31 to 2.34 and the mean weekly CrCl increased from 69.1 to 71.6 L/week/1.73m<sup>2</sup> from study period 1999 to study period 2000 (TABLE 16).
- 69% of patients had a mean hemoglobin ≥ 11 gm/dL during the 2000 study period compared to 62% in the 1999 study period (TABLE 17).
- The average hemoglobin for these patients increased from 11.4 gm/dL to 11.6 gm/dL from the 1999 study period to the 2000 study period (FIGURE 8).
- For the patients prescribed Epoetin, 58% had a mean hemoglobin of 11-12.9 gm/dL in the 2000 study period.
- 56% of patients had a mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP); only 17% of patients had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) during the 2000 study period (FIGURE 43).

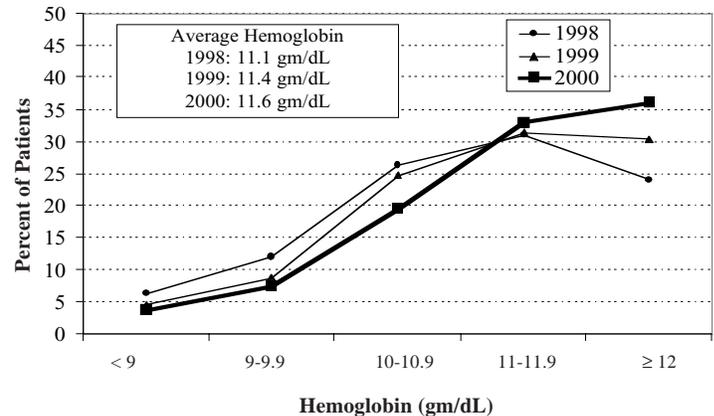
**Figure 6:** Distribution of mean weekly Kt/V<sub>urea</sub> values for adult (aged ≥ 18 years) CAPD patients, October 1999–March 2000 compared to November 1994–April 1995, November 1996–April 1997, and October 1998–March 1999. 2000 ESRD CPM Project.



**Figure 7:** Distribution of mean weekly creatinine clearance values (L/week/1.73m<sup>2</sup>) for adult (aged ≥ 18 years) CAPD patients, October 1999–March 2000 compared to November 1994–April 1995, November 1996–April 1997, and October 1998–March 1999. 2000 ESRD CPM Project.



**Figure 8:** Distribution of mean hemoglobin values for adult (aged ≥ 18 years) peritoneal dialysis patients October 1999–March 2000 compared to November 1997–April 1998 and October 1998–March 1999. 2000 ESRD CPM Project.



This report provides the dialysis community with an initial look at Network and national profiles of the clinical measures that were collected for the ESRD CPM Project. The project is not designed to allow for facility-specific profiles of care.

As you review this information, ask yourself the following:

What percent of adult patients at your facility are receiving adequate dialysis?

What percent of your patients have an average hemoglobin  $\geq 11$  gm/dL?

What percent of your patients have an average serum albumin  $\geq 4.0/3.7$  gm/dL (BCG/BCP)?

How do these CPMs or indicators of care for your patients compare to the indicators described in this report?

We want this report to stimulate questions such as these and, where indicated, to assist in developing ways to improve care to dialysis patients.

Copies of the initial results of the 2000 ESRD CPM Annual Report are distributed to all dialysis facilities for the purpose of stimulating facility efforts to improve care. Your Network staff and Medical Review Board are available to assist you in identifying and developing improvement efforts.

While significant improvements have occurred, the opportunity to improve care for adult in-center hemodialysis patients and adult peritoneal dialysis patients in the US in

the area of adequacy of dialysis continues. Every dialysis caregiver should be familiar with the clinical practice guidelines on adequacy of dialysis developed by the Renal Physicians Association (2) and the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF DOQI) (3,4). Factors that contribute to the inadequate delivery of dialysis are discussed in these documents. Efforts to improve the adequacy of dialysis should be attentive to these factors.

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

Recently, HCFA implemented a website entitled "Dialysis Facility Compare" which can be found at [www.medicare.gov](http://www.medicare.gov). This site provides dialysis facility-specific information to the public in an effort to assist ESRD patients and families in becoming informed consumers.

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

### 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 2001, we plan to provide a series of supplemental reports. In these reports we will provide more detailed analysis using data collected for the ESRD CPM Project as well as other data from which we can derive information about the patients in the sample identified for this project.

As you review 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 180 per million population and continues to rise at a rate of 7.8% per year (5). As of December 31, 1999, there were 259,493 patients receiving dialysis therapy in the United States (6).

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

The Health Care Financing Administration (HCFA), which oversees the Medicare program, contracts with 18 ESRD Network Organizations throughout the United States. The ESRD Networks perform oversight activities to assure the appropriateness of services and protection for ESRD patients. In 1994, HCFA, with input from the renal community, reshaped the approach of the ESRD Network program to quality assurance and improvement in order to respond to the need to improve the care of Medicare ESRD patients (7). This approach has been named the ESRD Health Care Quality Improvement Program (HCQIP).

The ESRD HCQIP gives the ESRD Networks and HCFA a chance to demonstrate that health care provided to renal Medicare beneficiaries can be measurably improved. The HCQIP is based on the assumption that most health care providers need and welcome both information and, where necessary, help in applying the tools and techniques of quality management (8).

#### ESRD Core Indicators Project

One activity included in the ESRD HCQIP was the National/Network ESRD Core Indicators Project (CIP). This project was initiated as a national intervention approach to assist dialysis providers in the improvement of patient care and outcomes. The ESRD CIP was HCFA's first nationwide population-based study designed to assess and identify opportunities to improve the care of patients with ESRD (9). 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 initiated in 1994 and in 1999 this project was merged with the ESRD Clinical Performance Measures Project.

### ESRD Clinical Performance Measures Project

Section 4558(b) of the Balanced Budget Act (BBA) of 1997 required HCFA to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, HCFA funded the development of Clinical Performance Measures (CPMs) based on the National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI) Clinical Practice Guidelines (3, 4, 10, 11).

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.hcfa.gov/quality/3m.htm](http://www.hcfa.gov/quality/3m.htm).

On March 1, 1999, the ESRD Core Indicators Project was merged with the ESRD CPM Project and this project is now known as the ESRD CPM Project. The ESRD CPMs are similar to the core indicators with the addition of measures for assessing vascular access.

This 2000 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; it does not provide results on a dialysis facility-specific basis. The quality of dialysis services is reported for adult in-center hemodialysis patients for the last quarter in 1999 and adult peritoneal dialysis patients for the time period October 1999–March 2000.

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

### 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 ESRD 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 (12). From 1994 to 1998, HCFA 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 (13-17).

The first data collection effort for the ESRD CPMs was conducted in 1999. It examined data from October–

December 1998 for in-center hemodialysis patients, and from October–December 1998 and January–March 1999 for peritoneal dialysis patients. Information to calculate the CPMs was collected and further opportunities to improve care were identified (18).

This report describes the findings from the second collection effort for the ESRD CPMs which was conducted in 2000 and collected data from October–December 1999 for in-center hemodialysis patients, and from October–December 1999 and January–March 2000 for 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 2000, a listing of adult (aged  $\geq 18$  years as of September 30, 1999) in-center hemodialysis and adult peritoneal dialysis patients who were alive and dialyzing on December 31, 1999, was obtained from each of the 18 ESRD Networks. The listing included, but was not limited to, the following information about each patient who met the project criteria: last name, first name, middle initial, date of birth, gender, race, Social Security and/or Health Insurance Claim number, underlying etiology of ESRD, date that dialysis was initiated, and provider number of the facility where the patient was dialyzing.

From this universe of patients, a national random sample, stratified by Network, of in-center hemodialysis patients was drawn. The sample size of in-center hemodialysis patients was selected to allow estimation of a proportion with a 95% confidence interval around that estimate no larger than 10 percentage points (i.e.,  $\pm 5\%$ ) for Network-specific estimates of the key Hemodialysis CPMs and 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 in-center hemodialysis patient population who were dialyzing at least six months prior to October 1, 1999. The final sample consisted of 8,697 in-center hemodialysis patients.

The peritoneal dialysis patient sample randomly selected 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 1,735 peritoneal dialysis patients.

A 5% national random sample of hemodialysis facilities was also drawn and consisted of 173 hemodialysis facilities. These facilities were surveyed to obtain information regarding post-dialysis BUN sampling, dialyzer reuse, and measurement of total cell volume of reprocessed dialyzers.

This year's data collection was unique in that it included all pediatric in-center hemodialysis patients 12-18 years of

age in each Network. A Supplemental Report describing the results of the data collected on the pediatric hemodialysis patients is planned for 2001.

## Data Collection

Three data collection forms were used: a five-page in-center hemodialysis form, a six-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 2000, 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 hemodialysis sample who received in-center hemodialysis at any time during October, November, and December 1999. Clinical information contained in the medical record was also abstracted for each patient in the peritoneal dialysis sample who was receiving peritoneal dialysis at any time during the two-month periods of October–November 1999, December 1999–January 2000, and February–March 2000.

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 2000, each Network sent a copy of their Visual FoxPro data files to ESRD Network 9/10 in Indianapolis, Indiana, where the data were aggregated and then submitted to HCFA, in an Epi Info, v.6.04a file (19), 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 (see note regarding statistics) 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.

## Note Regarding Statistics:

Readers may be interested to know if some of the patterns of clinical characteristics in this report show a statistically significant difference; e.g., comparisons among age groups, racial groups, or geographic areas. To assist readers, we have included 95% confidence interval (CI) brackets (I) on selected bar charts. If the upper limit of one group's bracket does not overlap with the lower limit of another group's bracket, then the difference between the two groups is statistically significant. In Figure 10, for example, the percentage of all women receiving adequate dialysis is statistically significantly higher than the percentage of all men receiving adequate dialysis.

## 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. 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 previous versions for clarification and to facilitate data analysis.

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

- I. The patient's delivered dose of hemodialysis is measured at least once per month.
- II. The patient's delivered dose of hemodialysis reported in the patient's chart is calculated by using formal urea kinetic modeling (UKM) or the Daugirdas II formula for  $Kt/V$ .
- 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 m<sup>2</sup> OR evidence that the dialysis prescription was changed if the adequacy measurements were below these thresholds.

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

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

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

- I. A primary arterial venous fistula (AVF) should be the access for at least 50% of all new patients initiating hemodialysis. A native AVF should be the primary access for 40% of all prevalent patients undergoing hemodialysis.
- II. Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for  $\geq 90$  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 is 11-12 gm/dL. Patients with a mean hemoglobin  $>12$  gm/dL and not prescribed Epoetin were excluded from analysis for this CPM.
- Ila. 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  $\geq 100$  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  $\geq 800$  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), mean hemoglobin values of 11–12.9 gm/dL for adult hemodialysis patients nationally and in each Network area, and mean hemoglobin values of 11–12.9 gm/dL nationally for peritoneal dialysis patients, and the percent of patients with mean hemoglobin < 10 gm/dL.

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

### Serum Albumin

Although serum albumin is not a CPM for this data collection period, it is one of the original core indicators and was chosen as an indicator for assessing mortality risk for adult in-center hemodialysis patients and adult peritoneal dialysis patients. 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 (20).

Mean serum albumin values < 3.5 gm/dL by the BCG method were defined as an indicator of inadequate serum albumin. Since the percent of mean serum albumin values < 3.2 gm/dL by the BCP method was nearly the same as the percent of mean serum albumin values < 3.5 gm/dL by the BCG method, we also defined a BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. Mean serum albumin values  $\geq 4.0$  gm/dL (BCG method) and  $\geq 3.7$  gm/dL (BCP method) were defined as indicators of optimal serum albumin.

Findings from this project allow us to report the percent of patients with mean serum albumin values  $\geq 3.5$  gm/dL (BCG method) and  $\geq 3.2$  gm/dL (BCP method) and the percent of patients with mean serum albumin values  $\geq 4.0$  gm/dL (BCG

method) and  $\geq 3.7$  gm/dL (BCP method) for hemodialysis patients in each Network area and nationally, and nationally for peritoneal dialysis patients.

## D. DATA ANALYSIS

### 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 8,154 of the 8,697 patients from the sample (response rate = 94%) (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 (21). Data regarding Epoetin use, serum ferritin concentrations, transferrin saturation levels, iron use, KUf (a measure of fluid removal), and actual time on dialysis were also analyzed. The initial analysis utilized Epi Info and Statistical Package for the Social Sciences (SPSS) software (19, 22).

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, KUf, blood pump flow rates, hemoglobin, transferrin saturation, serum ferritin concentration, prescribed Epoetin dose, and serum albumin. Information on prescription and route of administration of 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 Network areas), it was necessary to weight the collected data in order to obtain unbiased estimates of mean clinical values for the total population. This weighting was done according to the proportion of each Network's total population sampled. Aggregate national results shown in this report were derived from weighted data; Network-specific comparisons were derived from unweighted data.

**TABLE 1:** Number of adult (aged ≥ 18 years) in-center hemodialysis patients in each Network in December 1999, sample size and response rate for the 2000 ESRD CPM Project.

Network	# HD Patients Dec 1999	Sample Size	# Acceptable Forms <sup>^</sup>	Response Rate %
1	8,609	478	430	90.0
2	16,921	489	461	94.3
3	10,728	482	439	91.1
4	11,141	483	428	88.6
5	14,266	486	455	93.6
6	20,725	490	475	96.9
7	13,020	482	464	96.3
8	13,497	485	465	95.9
9	15,505	488	462	94.7
10	10,185	481	453	94.2
11	13,801	486	431	88.7
12	8,358	477	429	89.9
13	10,288	481	471	97.9
14	19,260	490	464	94.7
15	9,691	481	461	95.8
16	5,453	467	455	97.4
17	11,142	482	442	91.7
18	17,088	489	469	95.9
<b>Total</b>	<b>229,678</b>	<b>8,697</b>	<b>8,154</b>	<b>93.8</b>

<sup>^</sup> A form was considered acceptable if the patient met the selection criteria for inclusion in the study and if data were provided for at least one of the months in the fourth quarter of 1999 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 95% for serum albumin by either BCG or BCP method. Monthly hemoglobin values were available for 89% 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 93%. Monthly paired pre- and post-dialysis BUN values were available for 79% of patients.

**TABLE 2:** Characteristics of adult (aged ≥ 18 years) in-center hemodialysis patients in the 2000 ESRD CPM Project compared to those of all in-center hemodialysis patients in the US in 1998.

Patient Characteristic	2000 CPM Sample for Analysis		All US in 1998*	
	# <sup>^</sup>	%	# in 1000s	%
<b>TOTAL</b>	<b>8154</b>	<b>100</b>	<b>208.1</b>	<b>100</b>
<b>GENDER<sup>^^</sup></b>				
Men	4336	53	103.1	50
Women	3806	47	94.2	45
<b>RACE</b>				
American Indian/ Alaska Native	155	2	3.6	2
Asian/Pacific Islander	334	4	6.9	3
Black	2958	36	78.9	38
White	4444	55	103.9	50
Other/Unknown	263	3	14.8	7
<b>ETHNICITY</b>				
Hispanic	980	12		
Non-Hispanic	6739	83		
Other/Unknown	435	5		
<b>AGE GROUP<sup>^^^</sup> (years)</b>				
18-44	1399	17	31.3**	15
45-54	1401	17	31.0	15
55-64	1673	21	40.8	20
65-74	2065	25	51.9	25
75+	1616	20	41.3	20
<b>DIAGNOSIS</b>				
Diabetes mellitus	3258	40	75.7	36
Hypertension	2103	26	53.1	26
Glomerulonephritis	1006	12	21.2	10
Other/Unknown	1787	22	58.1	28
<b>DURATION of DIALYSIS (years)</b>				
<0.5	1080	13		
0.5-0.9	1072	13		
1.0-1.9	1617	20		
2.0+	4380	54		

\*USRDS: 2000 Annual Data Report, Bethesda, MD, National Institutes of Health, 2000.

<sup>^</sup> Subgroup totals may not equal 8,154 due to missing data.

<sup>^^</sup>USRDS data show 10,791 (5%) persons of unknown gender.

<sup>^^^</sup>USRDS data show 10,794 (5%) persons of unknown age.

\*\* For ages 20-44 years

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

## Peritoneal Dialysis

The initial analysis focused on the adequacy of dialysis CPMs, anemia management CPMs, and serum albumin values. Inclusion of a case for analysis required that the patient received peritoneal dialysis at least one month during the time period October 1999–March 2000. Of the 1,735 patients sampled, 1,603 patients were included for analysis (92% 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  $Kt/V_{\text{urea}}$ , weekly creatinine clearance, hemoglobin, serum albumin, prescribed Epoetin dose, serum ferritin concentrations, and transferrin saturation levels. Iron use for the patients in this sample was analyzed. The data are from a random sample, not stratified by Network; thus, only national aggregate data are reported. No Network-specific analyses were conducted.

**TABLE 3:** Number of adult (aged  $\geq 18$  years) peritoneal dialysis patients in each Network in December 1999, sample size and response rate for the 2000 ESRD CPM Project.

Network	# Peritoneal Dialysis Patients in December 1999	Sample Size	# Acceptable Forms <sup>^</sup>	Response Rate %
1	1280	91	80	87.9
2	1592	97	90	92.8
3	1411	78	72	92.3
4	1121	83	52	62.7
5	1576	105	96	91.4
6	2448	168	161	95.8
7	1214	64	62	96.9
8	1426	100	96	96.0
9	2474	159	143	89.9
10	1199	80	72	90.0
11	1880	123	116	94.3
12	1437	89	89	100.0
13	970	67	67	100.0
14	1590	85	76	89.4
15	1026	70	66	94.3
16	853	54	52	96.3
17	1444	96	88	91.7
18	1827	126	125	99.2
<b>Total</b>	<b>26768</b>	<b>1735</b>	<b>1603</b>	<b>92.4</b>

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

## E. 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 1999 for the in-center hemodialysis patients, and October 1999–March 2000 for the peritoneal dialysis patients.

The national results are presented separately in tables by gender, race, ethnicity, age groups (18-44, 45-54, 55-64, 65-74, and 75+ years of age), diagnosis of ESRD, and duration of dialysis. The diagnoses are categorized as diabetes mellitus (DM), hypertension (HTN), glomerulonephritis (GN), and other/unknown. In some instances clinical characteristics for patients in each Network area are also shown. Selected results are highlighted in figures. In addition, key findings from the 2000 CPM study period are compared to key findings from previous study periods.

**TABLE 4:** Characteristics of adult (aged  $\geq 18$  years) peritoneal dialysis patients in the 2000 ESRD CPM Project compared to those of all peritoneal dialysis patients in the US in 1998.

Patient Characteristic	2000 CPM Sample for Analysis		All US in 1999*	
	# <sup>^</sup>	%	# in 1000s	%
<b>TOTAL</b>	<b>1603</b>	<b>100</b>	<b>25.3</b>	<b>100</b>
GENDER <sup>^^</sup>				
Men	808	50	11.8	47
Women	788	49	11.5	46
RACE				
American Indian/ Alaska Native	18	1	0.4	1.6
Asian/Pacific Islander	81	5	1.0	4
Black	429	27	6.1	24
White	1006	63	15.3	61
Other/Unknown	69	4	2.5	10
ETHNICITY				
Hispanic	173	11		
Non-Hispanic	1372	86		
Other/Unknown	58	4		
AGE GROUP <sup>^^^</sup> (years)				
18-44	423	26	5.8**	23
45-54	375	23	4.7	19
55-64	355	22	4.9	19
65-74	316	20	4.9	19
75+	134	8	2.4	10
DIAGNOSIS				
Diabetes mellitus	545	34	7.6	30
Hypertension	338	21	4.7	19
Glomerulonephritis	306	19	4.0	16
Other/Unknown	414	26	9.0	36
DURATION of DIALYSIS (years)				
<0.5	332	21		
0.5-0.9	223	14		
1.0-1.9	331	21		
2.0+	716	45		

\*USRDS: 2000 Annual Data Report, Bethesda, MD, National Institutes of Health, 2000.

<sup>^</sup> Subgroup totals may not equal 1603 due to missing data.

<sup>^^</sup>USRDS data show 1922 (8%) persons of unknown gender.

<sup>^^^</sup>USRDS data show 1922 (8%) persons of unknown age.

\*\* For ages 20-44 years

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

## IN-CENTER HEMODIALYSIS PATIENTS

### 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 2000 project were:

To compare the prevalence of important clinical measures and/or characteristics of adult (aged  $\geq 18$  years) in-center hemodialysis patients in the US in October–December 1999 to the prevalence of those characteristics in the last quarter of each year (October–December) 1993 through 1998;

**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, 1999, was selected (sample size 8,697).

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 1999 for aggregation. This aggregated data file was then forwarded to HCFA for initial analysis.

- Initial Findings: The sample for analysis consisted of 8,154 patients which was 94% of the original sample. Highlights from the initial findings are summarized below.

### IMPROVEMENT OCCURRED

- 84% of the sampled patients were receiving dialysis with a delivered Kt/V  $\geq 1.2$ , an increase of four percentage points over 1999 (FIGURE 2).

- 83% of Black patients and 85% of White patients were receiving dialysis with a mean delivered Kt/V  $\geq 1.2$  in October–December 1999. This was a five percentage point increase for Black patients and a four percentage point increase for White patients from late 1998.
- 68% of patients had a mean hemoglobin  $\geq 11$  gm/dL in the last quarter of 1999 compared to 59% of the patients in the last quarter of 1998, a nine percentage point increase from late 1998 to late 1999 (FIGURE 4).
- 15% of Black patients and 10% of White patients had a mean hemoglobin  $< 10$  gm/dL in October–December 1999 compared to 18% and 15%, respectively, in October–December 1998.

### OPPORTUNITIES TO IMPROVE

- 16% of patients did not have a mean Kt/V  $\geq 1.2$  during the three-month study period.
- 40% of patients prescribed Epoetin did not have a mean hemoglobin of 11–12.9 gm/dL during the three-month study period.
- 68% of patients did not have a mean serum albumin  $\geq 4.0$  gm/dL (BCG method) or  $\geq 3.7$  gm/dL (BCP method) during the three-month study period.

### NEXT STEPS:

Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2001, 2002 and beyond. Recently, HCFA implemented a web site entitled “Dialysis Facility Compare” which can be found at [www.medicare.gov](http://www.medicare.gov). This site provides dialysis facility-specific information to the public in an effort to assist ESRD patients and families in becoming informed consumers.

### III. 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 1999 (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 1999; and (3) a comparison of CPM and/or other quality indicators results or findings for October–December 1999 and previous study periods. A national random sample of adult ( $\geq 18$  years) in-center hemodialysis patients, stratified by Network, who were alive on December 31, 1999, was selected ( $n=8697$ ). 8154 patients (94%) were included in the sample for analysis.

#### A. ADEQUACY OF HEMODIALYSIS

##### 1. CPM Findings for October–December 1999

Data to assess five hemodialysis adequacy CPMs were collected in 2000. The time period from which these data were abstracted was October–December 1999. Results for three of these CPMs are included in this 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:** 76% 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 1999). These measurements were recorded in the patient's chart, not calculated from individual data points. An additional 15% of the patients in the sample for analysis had documented adequacy measurements for two out of the three months, and another seven percent of the patients had documented adequacy measurements for one of the three months.

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

**FINDING:** 50% 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  $Kt/V \geq 1.2$ . 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 ( $n=5900$ ).

**FINDING:** For the last quarter of 1999, 90% 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 [ $n=5900$ ]) had a mean delivered hemodialysis dose of  $Kt/V \geq 1.2$ .

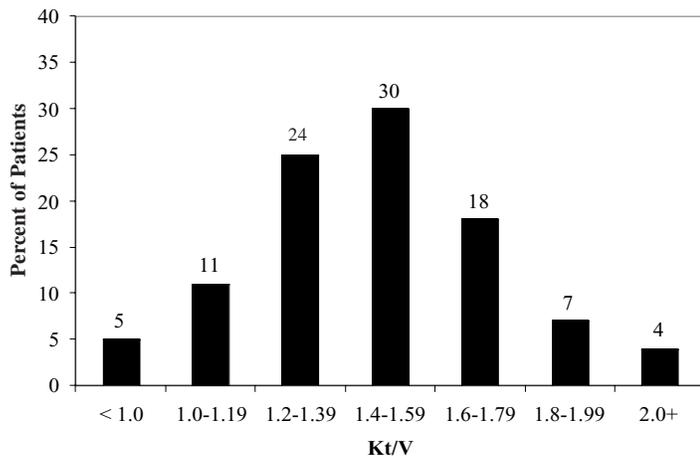
##### 2. Other Hemodialysis Adequacy Findings for October–December 1999

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

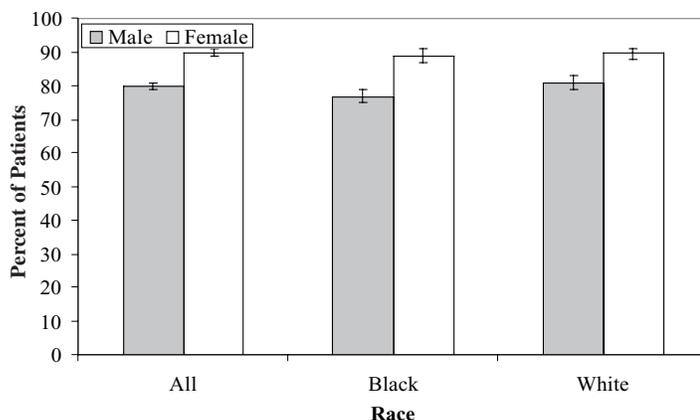
The mean delivered calculated Kt/V of all adult in-center hemodialysis patients in the sample for analysis in the last quarter of 1999 was 1.47. The distribution of Kt/V values for these patients is shown in Figure 9. The mean delivered calculated URR for this population was 69.9%. The mean Kt/V and the percent of patients with mean  $Kt/V \geq 1.2$  and  $Kt/V \geq 1.25$  for gender, race, ethnicity, age, diagnosis, duration of dialysis, and quintile of post-dialysis body weight are shown in Table 5.

The percent of patients in the sample for analysis with at least one calculated Kt/V measure available ( $n=7974$ ) who received adequate hemodialysis, defined as a mean  $Kt/V \geq 1.2$ , approximately equivalent to  $URR \geq 65\%$  (3, 5) in the last quarter of 1999 was 84% (TABLE 5, FIGURE 2). The percent of patients receiving hemodialysis with a mean  $Kt/V \geq 1.2$  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  $\geq 65$  years of age than for younger patients (TABLE 5, FIGURE 10).

**Figure 9:** Distribution of mean delivered Kt/V values for adult (aged ≥ 18 years) in-center hemodialysis patients, October–December 1999. 2000 ESRD CPM Project.



**Figure 10:** Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean delivered Kt/V ≥ 1.2, by race and gender, October–December 1999. 2000 ESRD CPM Project.



**TABLE 5:** Mean delivered Kt/V and percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean Kt/V ≥ 1.2 and Kt/V ≥ 1.25 by patient characteristics, October–December 1999. 2000 ESRD CPM Project.

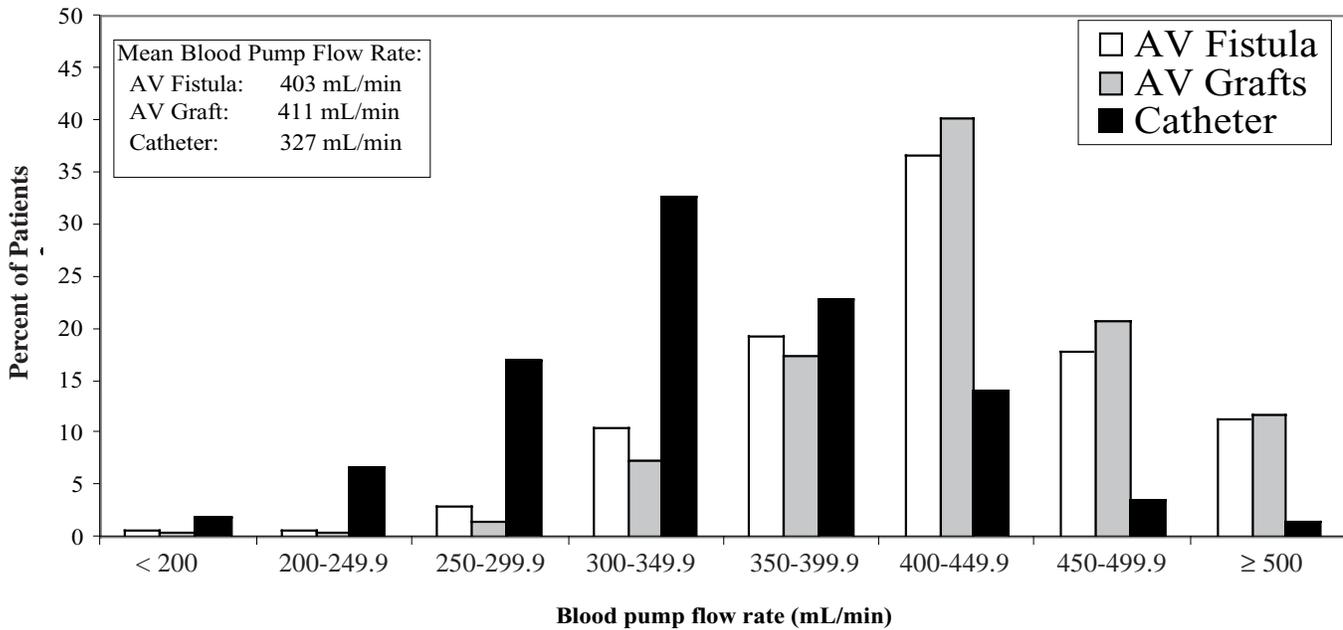
Patient Characteristics	Mean Kt/V	% Kt/V ≥ 1.2	% Kt/V ≥ 1.25
<b>TOTAL</b>	<b>1.47</b>	<b>84</b>	<b>80</b>
<b>GENDER</b>			
Men	1.40	80	74
Women	1.55	90	87
<b>RACE</b>			
American Indian/ Alaska Native	1.54	88	82
Asian/Pacific Islander	1.59	92	89
Black	1.44	83	77
White	1.49	85	81
Other/Unknown	1.48	84	79
<b>ETHNICITY</b>			
Hispanic	1.51	88	85
Non-Hispanic	1.47	84	79
<b>AGE GROUP (years)</b>			
18-44	1.43	80	74
45-54	1.44	80	75
55-64	1.46	85	80
65-74	1.50	87	84
75+	1.52	88	84
<b>DIAGNOSIS</b>			
Diabetes mellitus	1.46	84	80
Hypertension	1.47	84	79
Glomerulonephritis	1.47	84	80
Other/Unknown	1.50	86	83
<b>DURATION of DIALYSIS (years)</b>			
< 0.5	1.31	59	53
0.5-0.9	1.43	79	74
1.0-1.9	1.49	87	82
2.0+	1.52	91	87
<b>QUINTILE POST-DIALYSIS BODY WEIGHT (kg)</b>			
32.7-57.7	1.65	95	93
57.8-66.9	1.52	89	85
67.0-75.3	1.47	87	83
75.4-87.4	1.42	82	76
87.5-186.8	1.32	70	63

The mean time spent on dialysis per dialysis session was 214 minutes. The mean time spent on dialysis was somewhat longer for men than for women (222 minutes vs. 206 minutes), and for Blacks than for Whites (220 minutes vs. 211 minutes). The prescribed mean blood pump flow rate 60 minutes into the dialysis session was 403 mL/min for patients with an AVF, 411 mL/min for patients with either a synthetic or bovine graft, and 327 mL/min for patients with a catheter access during October–December 1999 (FIGURE 11). Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (24). 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 between delivered and prescribed blood flow to the dialyzer of 25% or more may exist at prescribed blood pump flow rates of 400 mL/min or more (25).

The percent of patients who received adequate hemodialysis varied significantly from one geographic region to another. Table 6 shows, by race and gender, the percent of patients who received hemodialysis with a mean delivered Kt/V  $\geq 1.2$  in each Network area; the percent ranged from 78% to 93% (FIGURES 12, 13).

**Figure 11:** Distribution of mean blood pump flow rates 60 minutes into the dialysis session for adult (aged  $\geq 18$  years) in-center hemodialysis patients, by access type, October–December 1999. 2000 ESRD CPM Project.



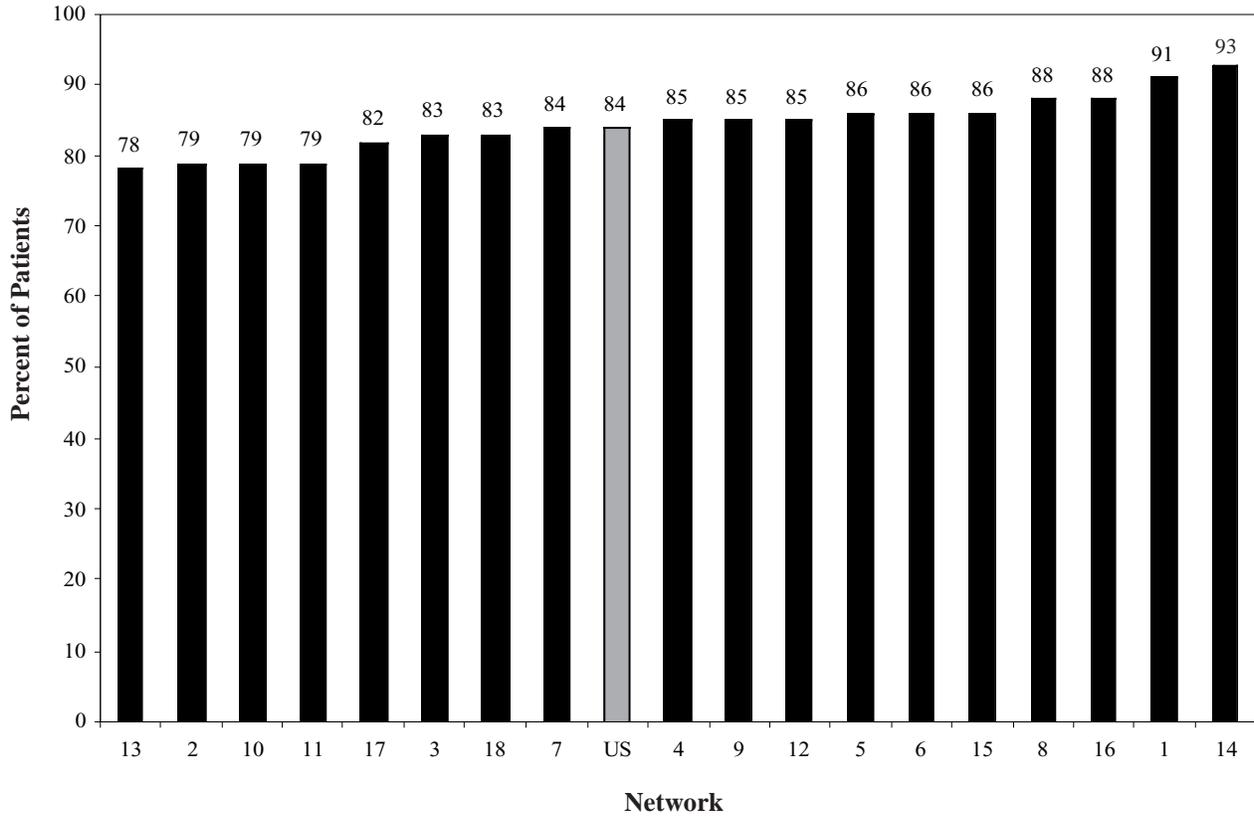
Note: Actual blood flow delivered to the dialyzer may be lower than the prescribed pump blood flow (24). This is particularly true for catheters where differences between delivered and prescribed blood flow to the dialyzer of 25% or more may exist at prescribed blood pump flow rates of 400 mL/min or more (25).

**TABLE 6:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients receiving dialysis with a mean delivered  $Kt/V \geq 1.2$ , by race, gender, and Network, October-December 1999, 2000 ESRD CPM Project.

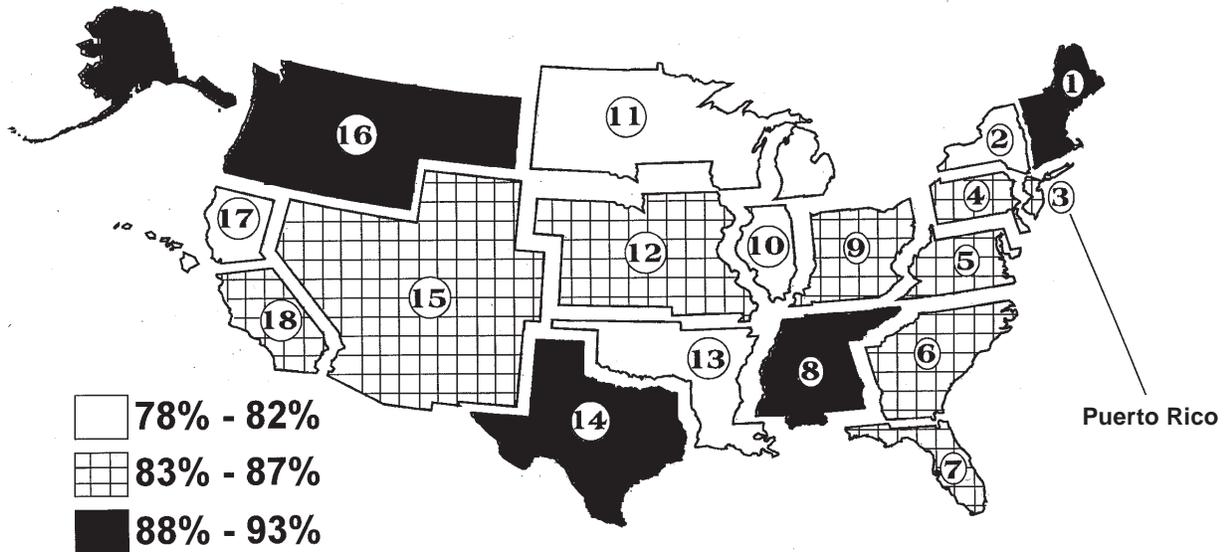
PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	91	79	83	85	86	86	84	88	85	79	79	85	78	93	86	88	82	83	84	
RACE																				
Black	92	73	80	85	88	88	82	89	82	76	76	82	76	89	69	89	72	79	83	
White	90	82	87	85	83	84	84	86	86	80	79	86	80	95	87	88	78	83	85	
MEN																				
Black	90	70	74	82	80	82	78	81	80	66	73	77	65	88	64	83	65	68	77	
White	88	81	83	80	75	79	79	84	84	75	73	84	68	91	82	85	73	81	81	
WOMEN																				
Black	94	77	87	89	96	94	85	96	86	87	81	87	85	91	77	100	81	86	89	
White	93	83	95	90	95	90	93	89	87	85	88	88	93	99	93	91	83	84	90	

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

**Figure 12:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients receiving dialysis with a mean delivered  $Kt/V \geq 1.2$ , by Network, October–December 1999. 2000 ESRD CPM Project.



**Figure 13:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients receiving dialysis with a mean delivered  $Kt/V \geq 1.2$ , by Network, October–December 1999. 2000 ESRD CPM Project.



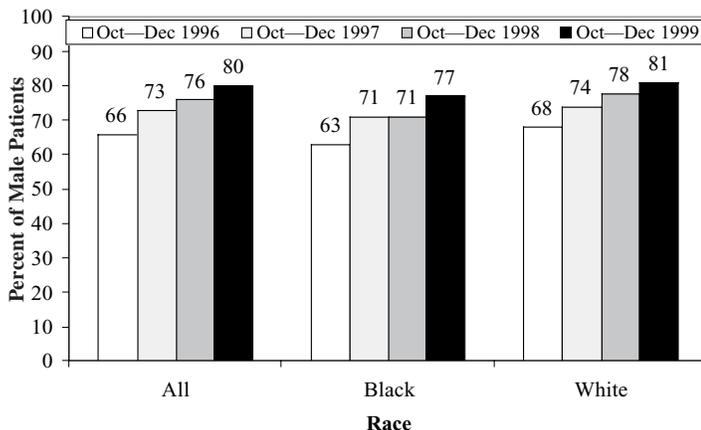
### 3. CPM and other Findings for October-December 1999 compared to previous study periods

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 delivered Kt/V in October-December 1999 was 1.47, an increase from previous study years. The percent of patients receiving dialysis with a mean delivered Kt/V  $\geq 1.2$  increased significantly from 80% in late 1998 to 84% in late 1999 (FIGURE 2). This significant improvement occurred for both men and women and for White and Black patients (FIGURES 14 and 15).

Nationally, this improvement means that approximately 9,000 patients were receiving hemodialysis with a mean Kt/V  $\geq 1.2$  in late 1999 who would not have received this level of dialysis had they been dialyzing one year earlier (FIGURE 2).

**Figure 14:** Percent of adult (aged  $\geq 18$  years) male in-center hemodialysis patients with mean delivered Kt/V  $\geq 1.2$ , by race, October–December 1999 compared to October–December 1996, 1997, and 1998. 2000 ESRD CPM Project.



**Figure 15:** Percent of adult (aged  $\geq 18$  years) female in-center hemodialysis patients with mean delivered Kt/V  $\geq 1.2$ , by race, October–December 1999 compared to October–December 1996, 1997, and 1998. 2000 ESRD CPM Project.

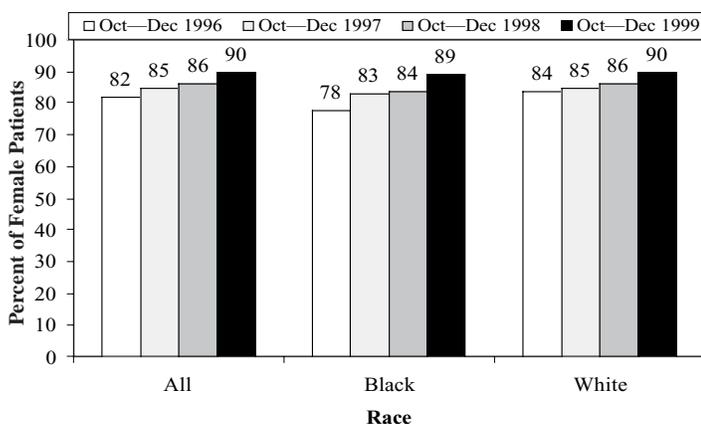
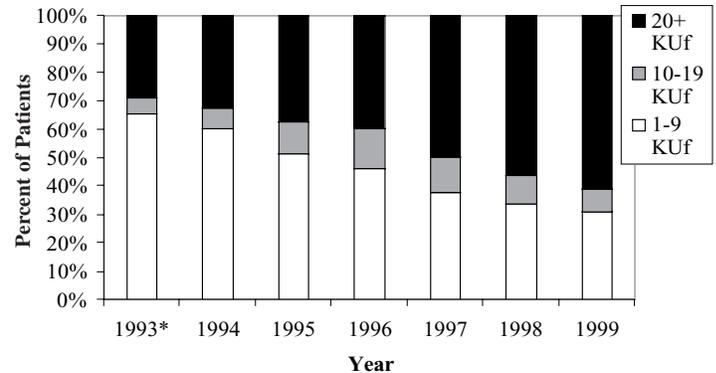


Figure 16 shows the percent of adult in-center hemodialysis patients dialyzed by dialyzer KUF category October–December 1999, compared to October–December 1993, 1994, 1995, 1996, 1997, and 1998.

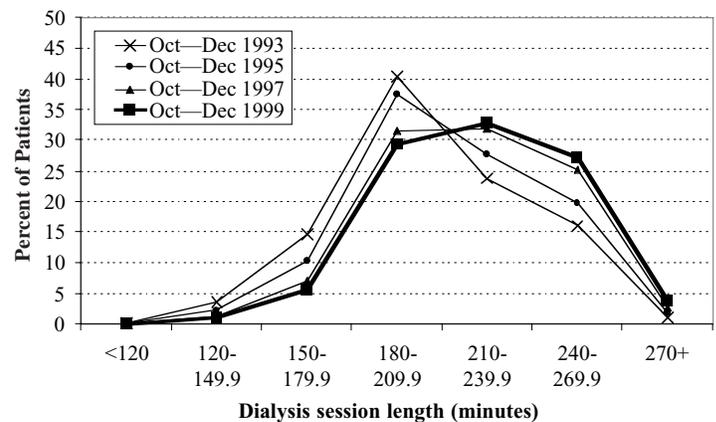
Figure 17 shows a trend for slight increases in dialysis session lengths from late 1993 to late 1999.

**Figure 16:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients dialyzed by dialyzer KUF category, October–December 1999 compared to October–December 1993, 1994, 1995, 1996, 1997, and 1998. 2000 ESRD CPM Project.



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

**Figure 17:** Distribution of mean dialysis session length (minutes), October–December 1999 compared to October–December 1993, 1995, and 1997. 2000 ESRD CPM Project.



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

## B. VASCULAR ACCESS

### 1. CPM Findings for October-December 1999

Data to assess three vascular access CPMs were collected in 2000. The time period from which these data were abstracted was October–December 1999. 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:** 28% of incident patients (initiating their most recent course of hemodialysis, on or between January 1, 1999, and August 31, 1999, [n = 1399]) were dialyzed using an AVF during October–December 1999. 27% of all patients in the sample for analysis were dialyzed using an AVF during October–December 1999.

**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:** 14% of all patients in the sample for analysis were dialyzed with a chronic catheter continuously for 90 days or longer during October–December 1999.

**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:** 45% of patients with an AV graft (n=3911) had this graft routinely monitored for the presence of stenosis during October–December 1999.

**TABLE 7:** Vascular access type for incident\* and all adult (aged ≥ 18 years) in-center hemodialysis patients, by selected patient characteristics, October-December 1999. 2000 ESRD CPM Project.

Patient Characteristic	Incident (n=1399)			All (n=8154)		
	AVF %	Graft %	Catheter %	AVF %	Graft %	Catheter %
<b>TOTAL</b>	<b>28</b>	<b>43</b>	<b>30</b>	<b>27</b>	<b>50</b>	<b>23</b>
<b>GENDER</b>						
Men	36	39	25	35	44	21
Women	18	47	36	18	57	26
<b>RACE</b>						
American Indian/ Alaska Native	33	40	27	37	48	16
Asian/Pacific Islander	37	39	24	31	55	14
Black	20	47	32	23	56	22
White	30	41	29	29	46	25
Other/Unknown	33	29	39	38	35	27
<b>ETHNICITY</b>						
Hispanic	32	43	25	29	51	20
Non-Hispanic	27	42	30	27	50	23
<b>AGE GROUP (years)</b>						
18-44	33	32	35	35	40	24
45-54	30	43	26	31	48	21
55-64	26	43	31	26	52	22
65-74	24	49	27	23	56	22
75+	27	42	31	23	51	27
<b>DIAGNOSIS</b>						
Diabetes Mellitus	26	50	25	22	55	23
Hypertension	30	36	34	28	49	23
Glomerulonephritis	32	36	32	36	44	20
Other/Unknown	28	37	35	30	45	25
<b>DURATION of DIALYSIS (years)</b>						
< 0.5	21	42	37	16	32	52
0.5-0.9	30	43	28	29	43	28
1.0-1.9	N/A	N/A	N/A	28	51	21
2.0+	N/A	N/A	N/A	28	56	16

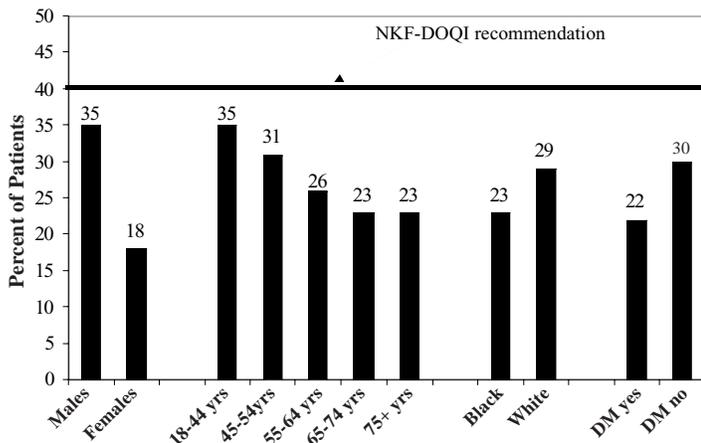
\* An incident patient is defined as a patient initiating in-center hemodialysis on or between January 1, 1999 and August 31, 1999.

## 2. Other Vascular Access Findings for October-December 1999

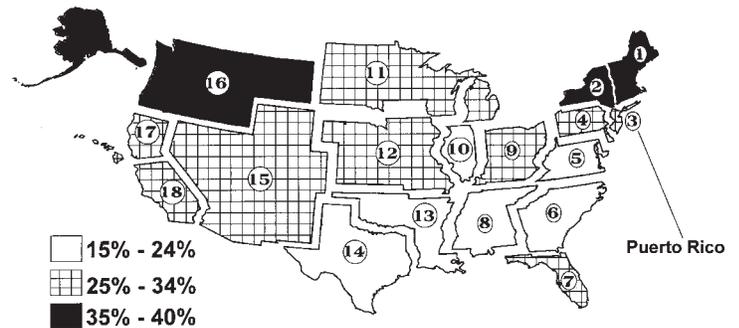
28% of incident and 27% of all patients in the sample for analysis were dialyzed with an AV fistula during October–December 1999. More men, Whites, patients 18-44 years old, non-diabetics, and patients dialyzing six months or longer were dialyzed with an AV fistula compared to women, Blacks, patients older than 44 years, diabetics, and patients dialyzing less than six months (TABLE 7). Regardless of patient characteristics, all patient groups examined were below the current DOQI recommendation of 40% of prevalent patients having an AV fistula as their vascular access (FIGURE 18).

There was wide geographic variation in the percent of patients dialyzed with an AV fistula; the percent ranged from 15% to 40% among the 18 Network areas (FIGURE 19, TABLE 8). There was also variation in the percent of patients dialyzed with a catheter, ranging from 15% to 30% among Networks (FIGURE 20).

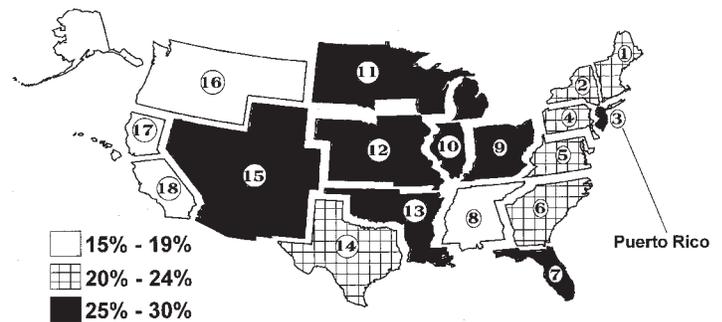
**Figure 18:** Percent of all adult (aged ≥ 18 years) in-center hemodialysis patients dialyzed with an AV fistula on their last hemodialysis session during October-December 1999, by patient characteristics. 2000 ESRD CPM Project.



**Figure 19:** Percent of all adult (aged ≥ 18 years) in-center hemodialysis patients dialyzed with an AV fistula as their vascular access on their last hemodialysis session during October–December 1999, by Network. 2000 ESRD CPM Project.



**Figure 20:** Percent of all adult (aged ≥ 18 years) in-center hemodialysis patients dialyzed with a catheter as their vascular access on their last hemodialysis session during October–December 1999, by Network. 2000 ESRD CPM Project.



**TABLE 8:** Percent of all adult (aged  $\geq 18$  years) in-center hemodialysis patients with an AV fistula access on their last hemodialysis session during October–December 1999, by race, gender, age, and Network. 2000 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	40	35	34	28	22	24	29	22	27	24	27	32	18	15	30	40	32	25	27	
RACE																				
Black	32	29	33	23	19	24	29	23	21	21	21	29	15	13	*	39	28	19	23	
White	41	38	35	30	23	25	29	22	31	26	30	32	22	17	29	41	35	25	29	
GENDER																				
Men	49	44	41	33	31	31	35	30	36	32	37	40	28	21	37	50	44	36	35	
Women	28	23	23	22	12	16	23	15	20	15	16	22	9	10	22	26	19	15	18	
AGE GROUP (years)																				
18-44	58	43	47	32	24	33	42	36	34	29	43	39	22	21	36	48	41	32	35	
45-54	38	39	30	35	30	33	33	28	30	24	30	44	28	13	34	42	34	31	31	
55-64	43	32	33	27	19	22	32	22	25	20	26	33	17	18	28	39	30	22	26	
65-74	36	28	34	27	20	19	23	13	23	24	22	23	10	13	26	32	28	29	23	
75+	33	35	25	21	16	18	21	17	27	21	21	25	15	13	30	41	32	13	23	

\* Value suppressed because  $n \leq 10$

Table 9 depicts the odds ratio (95% CI) for a patient having an AV fistula as his/her vascular access 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 patient 18-44 years old has a 1.6 (or 60%) greater chance of having an AV fistula as his/her vascular access compared to a patient 45 years old or older (without controlling for any other variables).

23% (n=1867) of all patients in the sample for analysis were dialyzed with a catheter during the last hemodialysis session of the study period (TABLE 7). Within this subset of patients, 32% had no fistula or graft surgically created, 21% had a fistula or graft maturing (not ready to cannulate), 20% had all fistula or graft sites in their body exhausted, 13% had a temporary interruption of a fistula or graft due to clotting or revisions, and 14% of patients had a catheter for "Other/Unknown" reasons. A higher percent of patients dialyzing less than six months compared to those patients dialyzing six months or longer were dialyzed with a catheter (TABLE 7).

46% of patients with an AV fistula or a graft (n=6146) had their vascular access monitored for stenosis during the study period. For this subset of patients, 61% were monitored with dynamic venous pressure, 13% with static venous pressure, 9% with the dilution technique, 8% with Color-Flow Doppler, and 23% with "Other" techniques (groups not mutually exclusive).

### 3. CPM and Other Findings for October-December 1999 compared to previous study periods.

More patients were dialyzed with a catheter during October-December 1999 compared to October-December 1998 (23% vs. 19%, respectively) (FIGURE 21). A similar pattern was noted for incident patients, with 30% of incident patients in late 1999 dialyzed with a catheter compared to 24% in late 1998.

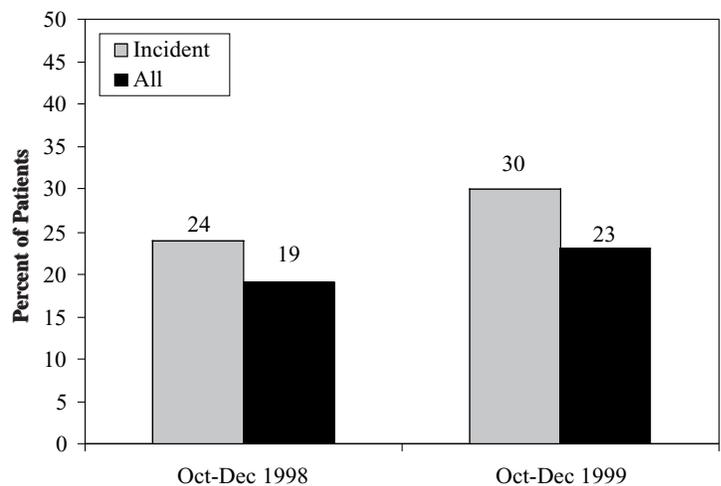
There was very little change in the percent of all patients dialyzed with an AV fistula from late 1998 compared to late 1999 (26% vs. 27%, respectively). Similarly, 26% of incident patients were dialyzed with an AV fistula in late 1998 compared to 28% in late 1999.

14% of patients were dialyzed with a chronic catheter continuously for 90 days or longer during October-December 1998 and during October-December 1999.

**TABLE 9:** Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for having an AV fistula access, October–December 1999, 2000 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
<b>GENDER</b>	
Female	0.39 (0.35, 0.43)
Male (referent)	
<b>RACE</b>	
Black	0.69 (0.62, 0.77)
White (referent)	
<b>AGE GROUP (years)</b>	
18-44	1.6 (1.4, 1.8)
45+ (referent)	
<b>DIABETES MELLITUS</b>	
Yes	0.65 (0.59, 0.72)
No (referent)	
<b>QUINTILE POST-DIALYSIS BODY WEIGHT</b>	
Quintile 2	1.2 (1.1, 1.5)
Quintile 3	1.3 (1.1, 1.5)
Quintile 4	1.3 (1.1, 1.5)
Quintile 5 (highest)	1.1 (0.90, 1.2)
Quintile 1 (referent)	

**Figure 21:** Percent of adult (aged ≥ 18 years) in-center hemodialysis patients (all and incident) dialyzed with a catheter on their last hemodialysis session during October-December 1999 compared to October–December 1998. 2000 ESRD CPM Project.



## C. ANEMIA MANAGEMENT

### 1. CPM and Other Findings for October–December 1999

Data to assess three anemia management CPMs were collected in 2000. The time period from which these data were abstracted was October–December 1999.

**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 1999, 59% of the in-center hemodialysis patients who met the inclusion criteria (n=7914) had a mean hemoglobin 11–12.9 gm/dL.

**Anemia Management CPM IIa** — 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 1999, 89% of the in-center hemodialysis patients who met the inclusion criteria (n=7880) 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  $\geq 100$  ng/mL and at least one transferrin saturation  $\geq 20\%$  were documented during the three-month study period.

**FINDING:** For the last quarter of 1999, 66% of the in-center hemodialysis patients who met the inclusion criteria (n=7880) had at least one documented transferrin saturation  $\geq 20\%$  and at least one documented serum ferritin concentration  $\geq 100$  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  $\geq 800$  ng/mL; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

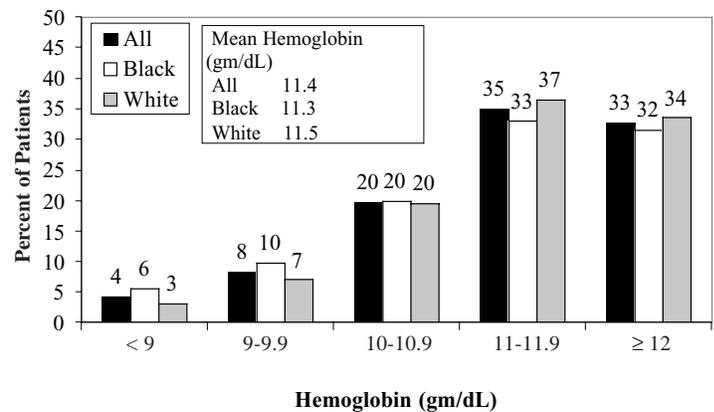
**FINDING:** 67% of the in-center hemodialysis patients who met the inclusion criteria (n=3198) were prescribed intravenous iron in at least one month during October–December 1999.

### 2. Other Anemia Management Findings for October-December 1999

**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 22 for both Black and White patients. The mean hemoglobin value for all patients in this sample was 11.4 gm/dL. The mean hemoglobin values for gender, race, ethnicity, age, diagnosis, and duration of dialysis are shown in Table 10. The mean hemoglobin value was lower for women, Blacks, non-Hispanics, patients dialyzing less than six months, and patients 18-44 years old compared to men, Whites, Hispanics, patients dialyzing six months or longer, and patients older than 44 years.

**Figure 22:** Distribution of mean hemoglobin values for adult (aged  $\geq 18$  years) in-center hemodialysis patients in the US, by race, October–December 1999. 2000 ESRD CPM Project.



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

**TABLE 10:** Mean hemoglobin values (gm/dL) for adult (aged ≥ 18 years) in-center hemodialysis patients in the US, by patient characteristics, October–December 1999. 2000 ESRD CPM Project.

Patient Characteristic	Mean Hemoglobin (gm/dL)	% of patients with Hemoglobin values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
<b>TOTAL</b>	<b>11.4</b>	<b>4</b>	<b>8</b>	<b>20</b>	<b>35</b>	<b>33</b>
<b>GENDER</b>						
Men	11.5	4	8	19	34	35
Women	11.3	5	8	21	37	30
<b>RACE</b>						
American Indian/ Alaska Native	11.7	3	6	18	37	36
Asian/Pacific Islander	11.4	4	7	22	36	32
Black	11.3	6	10	20	33	32
White	11.5	3	7	20	37	34
Other/Unknown	11.4	7	11	19	34	29
<b>ETHNICITY</b>						
Hispanic	11.5	4	7	18	36	36
Non-Hispanic	11.4	4	9	20	35	32
<b>AGE GROUP (years)</b>						
18-44	11.3	7	11	19	30	34
45-54	11.4	5	8	20	35	32
55-64	11.4	4	9	20	36	32
65-74	11.5	4	7	20	37	33
75+	11.5	2	7	21	36	33
<b>DIAGNOSIS</b>						
Diabetes mellitus	11.4	3	8	19	37	32
Hypertension	11.4	4	8	21	34	33
Glomerulonephritis	11.5	3	9	18	36	33
Other/Unknown	11.4	6	8	20	33	33
<b>DURATION of DIALYSIS (years)</b>						
< 0.5	10.8	12	16	25	24	22
0.5-0.9	11.6	3	6	18	36	36
1.0-1.9	11.5	3	6	18	38	35
2.0+	11.5	3	8	20	37	33

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

The percent of patients with mean hemoglobin < 9 gm/dL was 4%. The percent of patients with mean hemoglobin < 10 gm/dL was 12%. 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 (26). The prevalence of patients with mean hemoglobin < 10 gm/dL ranged from 8% to 18% among Networks (FIGURE 23).

**Figure 23:** Percent of adult (aged ≥ 18 years) in-center hemodialysis patients with mean hemoglobin < 10gm/dL, by Network, October–December 1999. 2000 ESRD CPM Project.

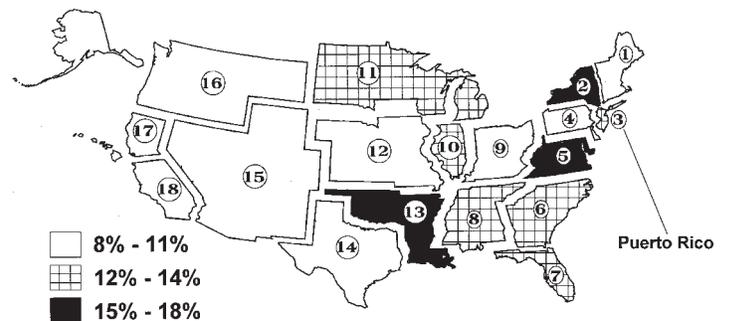
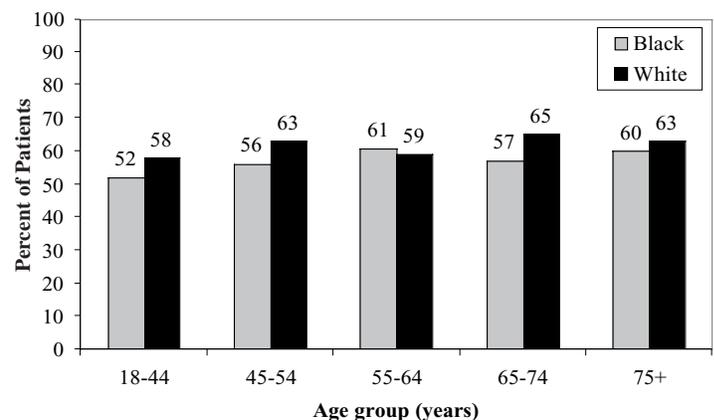


Table 11 shows, by Network, race, gender, and age group, the percent of patients prescribed Epoetin with hemoglobin values 11–12.9 gm/dL. The percent of all patients prescribed Epoetin with mean hemoglobin 11–12.9 gm/dL was 60% nationally and ranged from 48% to 68% by Network (TABLE 11). The percent of all patients prescribed Epoetin, with mean hemoglobin 11–12.9 gm/dL by race and age group, is shown in Figure 24. The percent of all patients with mean hemoglobin ≥ 11 gm/dL was 68% nationally and ranged from 57% to 74% by Network (FIGURES 25, 26).

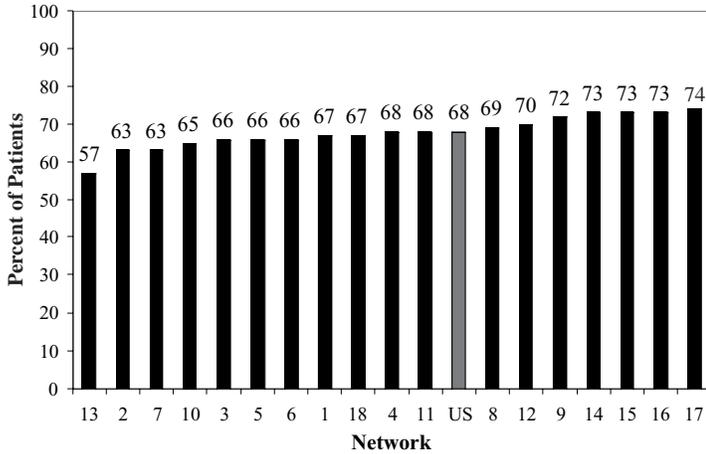
**Figure 24:** Percent of adult (aged ≥ 18 years) in-center hemodialysis patients prescribed Epoetin with mean hemoglobin 11–12.9 gm/dL, by age and race, October–December 1999. 2000 ESRD CPM Project.



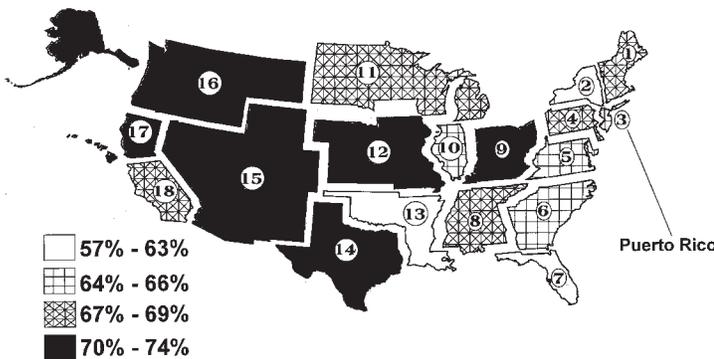
**TABLE 11:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients prescribed Epoetin with mean hemoglobin 11-12.9 gm/dL, by race, gender, age, and Network, October-December 1999. 2000 ESRD CPM Project.

PATIENT CHARACTERISTIC	NETWORK																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	US	
ALL	59	56	56	64	59	58	57	60	61	55	63	62	48	66	57	61	68	62	60	
RACE																				
Black	54	54	54	57	59	59	52	59	57	53	49	61	48	64	52	56	64	63	57	
White	61	56	61	67	59	60	60	61	64	58	68	62	48	68	59	62	68	62	62	
GENDER																				
Men	61	53	57	62	60	59	58	63	59	56	63	64	48	62	55	56	70	62	59	
Women	58	60	53	65	57	60	55	57	64	55	62	60	48	69	61	67	65	62	60	
AGE GROUP (years)																				
18-44	55	49	47	56	56	56	53	63	54	53	54	55	47	50	53	64	64	64	55	
45-54	54	55	58	63	59	55	49	60	60	56	62	61	46	66	68	57	66	63	59	
55-64	57	60	56	57	63	58	61	64	57	53	57	62	49	67	55	60	64	58	59	
65-74	63	59	53	65	64	59	59	54	65	57	68	68	48	71	54	60	71	66	62	
75+	62	56	62	72	51	64	58	61	67	58	67	63	47	72	61	63	73	60	62	

**Figure 25:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean hemoglobin  $\geq 11$  gm/dL, by Network, October–December 1999. 2000 ESRD CPM Project.



**Figure 26:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean hemoglobin  $\geq 11$  gm/dL, by Network, October–December 1999. 2000 ESRD CPM Project.



Because patients could have Epoetin prescribed during one project month but not during another, we were not able to correlate Epoetin use with the mean hemoglobin values. Instead, we assessed Epoetin use at the time of each of the 23,209 hemoglobin determinations reported in this project. Overall, Epoetin was prescribed 95% of the time when a hemoglobin value was determined.

During this study period, data were collected on additional measures useful for anemia management (TABLE 12).

The national average transferrin saturation for the patients in the sample was 28.4% and ranged from 25.5% to 33.3% among the 18 Network areas (TABLE 12). Table 12 also provides the percent of patients with mean transferrin saturation  $\geq 20\%$  nationally (68%) and by Network area, ranging from 57% to 79%.

The national average serum ferritin concentration for the patients in the sample was 489 ng/mL and ranged from 400 to 585 ng/mL among the 18 Network areas. The percent of patients with a mean serum ferritin concentration  $\geq 100$  ng/mL nationally was 80%, ranging from 72% to 86% among the 18 Network areas (TABLE 12).

70% 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 61%, ranging from 53% to 71% among the 18 Network areas (TABLE 12).

For the subset of patients with both mean transferrin saturation  $< 20\%$  and mean serum ferritin concentration  $< 100$  ng/mL ( $n=517$  or 6% of patients), only 48% were prescribed IV iron at least once during the three-month study period.

Of the patients prescribed Epoetin, 89% were prescribed Epoetin by the IV route; and 12% by the subcutaneous route (groups not mutually exclusive). Prescribed subcutaneous administration, the route recommended by the NKF DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure (10), ranged from 4% to 30% among the 18 Network areas (TABLE 12).

**TABLE 12:** Regional variation for various anemia management measures for adult (aged ≥ 18 years) 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<sup>^</sup>, for these patients nationally and by Network, October-December 1999. 2000 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	67	63	66	68	66	66	63	69	72	65	68	70	57	73	73	73	74	67	68
Mean hemoglobin (gm/dL)	11.4	11.2	11.4	11.4	11.3	11.4	11.3	11.4	11.6	11.4	11.4	11.4	11.2	11.6	11.8	11.7	11.6	11.4	11.4
Percent of patients with mean serum albumin ≥4.0 gm/dL <sup>^</sup>	35	38	30	28	28	30	27	31	28	30	31	31	27	27	33	30	39	30	30
Average transferrin saturation (%)	26.9	27.4	28.4	28.1	26.5	30.0	28.1	28.0	28.2	29.8	28.2	25.5	26.2	28.4	28.1	27.4	27.8	33.3	28.4
Percent of patients with mean transferrin saturation ≥ 20%	68	62	67	64	64	76	67	57	64	73	65	63	61	79	68	69	73	76	68
Average serum ferritin concentration (ng/mL)	457	400	497	447	429	527	585	490	503	443	452	457	492	533	469	477	518	551	489
Percent of patients with mean serum ferritin concentration ≥ 100 ng/mL	78	72	77	73	75	83	79	84	80	74	78	78	82	86	82	80	84	82	80
Percent of patients with IV iron prescribed	56	53	56	58	56	59	60	59	71	62	63	61	69	63	60	63	61	59	61
Percent of patients * with subcutaneous Epoetin prescribed	8	4	12	6	5	4	8	4	30	16	21	19	11	17	7	16	13	18	12
Percent of patients with mean hemoglobin <11 gm/dL with Epoetin prescribed	97	98	96	98	95	93	95	95	95	93	95	96	97	94	96	94	97	94	95

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

\*Among patients prescribed Epoetin

Table 13 depicts the odds ratio (95% CI) for experiencing a mean hemoglobin < 11 gm/dL by several patient and clinical characteristics. The logistic regression analyses were conducted separately for each characteristic examined; the referent category is noted in each case. For example, a female has a 1.1 (or 10%) greater chance of experiencing a mean hemoglobin < 11 gm/dL than a male (without controlling for any other variables).

**TABLE 13:** Independent logistic regression analyses by selected patient and clinical characteristics to predict odds ratio (95% CI) for mean hemoglobin < 11 gm/dL. 2000 ESRD CPM Project.

Characteristic	Odds Ratio (95% CI)
<b>GENDER</b>	
Female	1.1 (1.04, 1.3)
Male (referent)	
<b>RACE</b>	
Black	1.3 (1.2, 1.5)
White (referent)	
<b>ETHNICITY</b>	
Hispanic	0.83 (0.71, 0.96)
Non-Hispanic (referent)	
<b>AGE GROUP (years)</b>	
18-44	1.2 (1.1, 1.4)
45+ (referent)	
<b>DIABETES MELLITUS</b>	
Yes	0.91 (0.83, 0.99)
No (referent)	
<b>MEAN Kt/V</b>	
< 1.2	2.0 (1.7, 2.2)
≥ 1.2 (referent)	
<b>MEAN SERUM ALBUMIN</b>	
< 3.5/ < 3.2 gm/dL (BCG/BCP)*	2.7 (2.4, 3.0)
≥ 3.5/ ≥ 3.2 gm/dL (BCG/BCP) (referent)	
<b>EPOETIN</b>	
prescribed during study period not prescribed (referent)	1.2 (0.97, 1.5)
<b>DURATION OF DIALYSIS (years)</b>	
< 0.5	2.8 (2.4, 3.2)
≥ 0.5 years (referent)	
<b>MEAN TRANSFERRIN SATURATION</b>	
< 20%	2.1 (1.9, 2.3)
≥ 20% (referent)	
<b>MEAN SERUM FERRITIN CONCENTRATION</b>	
< 100 ng/mL	1.5 (1.4, 1.7)
≥ 100 ng/mL (referent)	

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

### 3. CPM and Other Findings for October-December 1999 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 from October–December 1998 to October–December 1999 increased from 11.1 gm/dL to 11.4 gm/dL, and the percent of patients with a mean hemoglobin ≥ 11 gm/dL increased significantly from 59% to 68% (FIGURES 4, 5, 27).

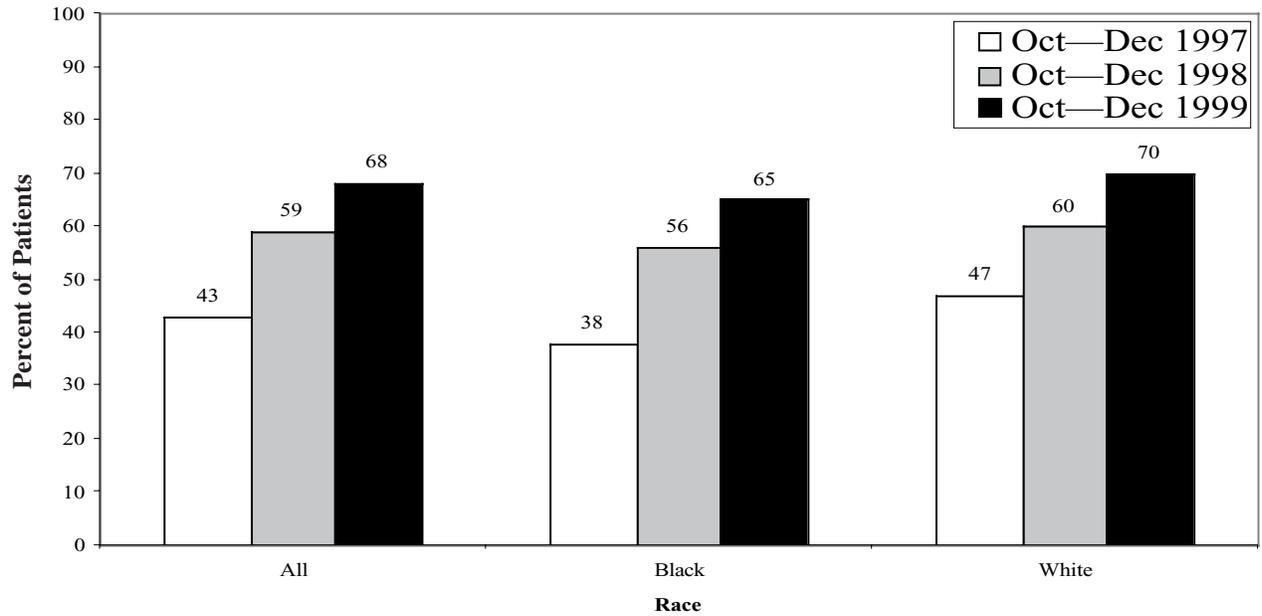
In addition to the improvement in the percent of patients with mean hemoglobin ≥ 11 gm/dL, there was also a decrease in the percent of patients with mean hemoglobin < 10 gm/dL. In October–December 1998, 18% of Black patients and 15% of White patients had a mean hemoglobin < 10 gm/dL, while in October–December 1999, 15% of Black patients and 10% of White patients had a mean hemoglobin < 10 gm/dL.

The percent of patients prescribed Epoetin by hemoglobin category in late 1997, 1998, and 1999 is shown in Figure 28. 12% of patients were prescribed subcutaneous Epoetin in late 1999, no change from late 1998.

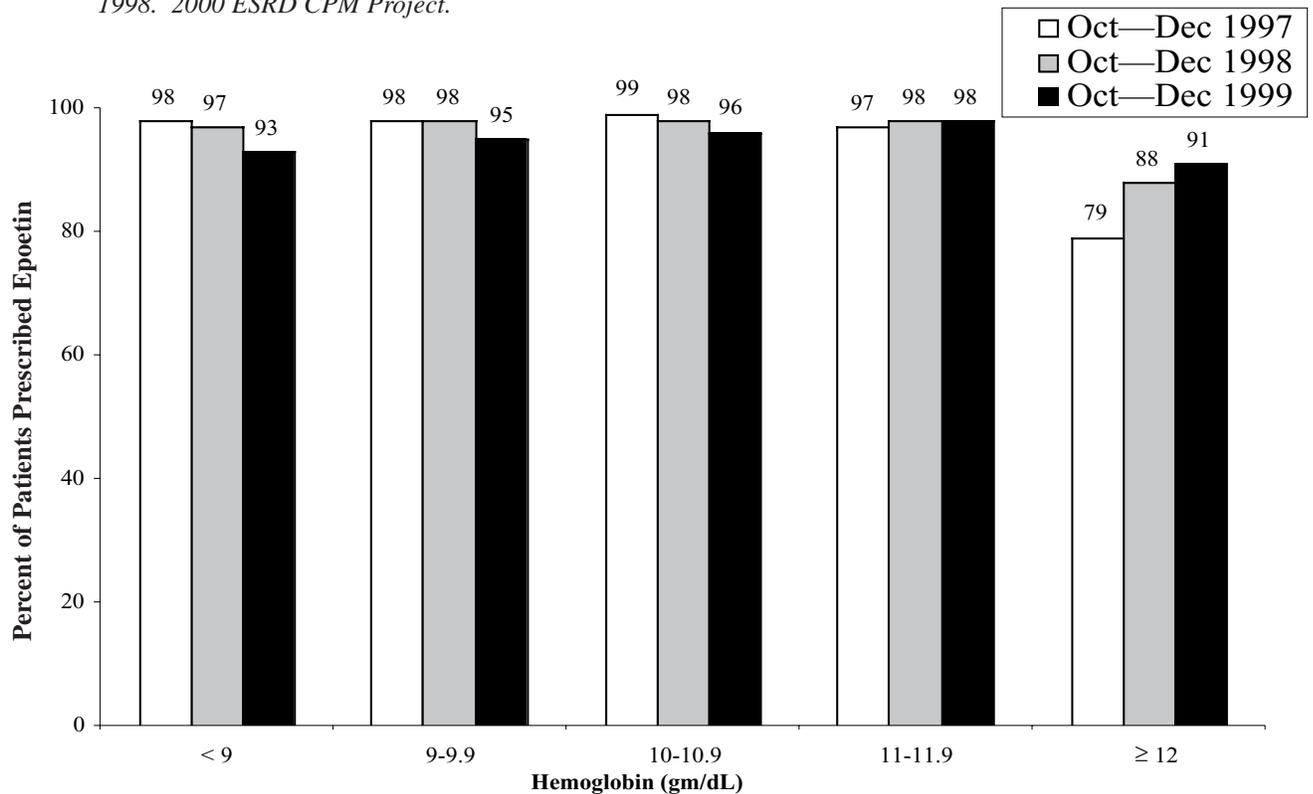
Figure 29 depicts the trend in Epoetin dosing (units/kg/dose) from late 1997 to late 1999. In all three years, subcutaneous Epoetin doses were systematically lower than the intravenous Epoetin doses at all hemoglobin categories examined.

Figure 30 depicts the status of iron stores for the sampled patients in late 1999 compared to late 1996 through late 1998. Overall, 61% of patients were prescribed IV iron in late 1999 compared to 51% in late 1996. Within the subgroup of patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL, 48% of patients were prescribed IV iron at least once over the three-month study period in late 1999, compared to 52% in late 1998, 40% in late 1997 and 37% in late 1996.

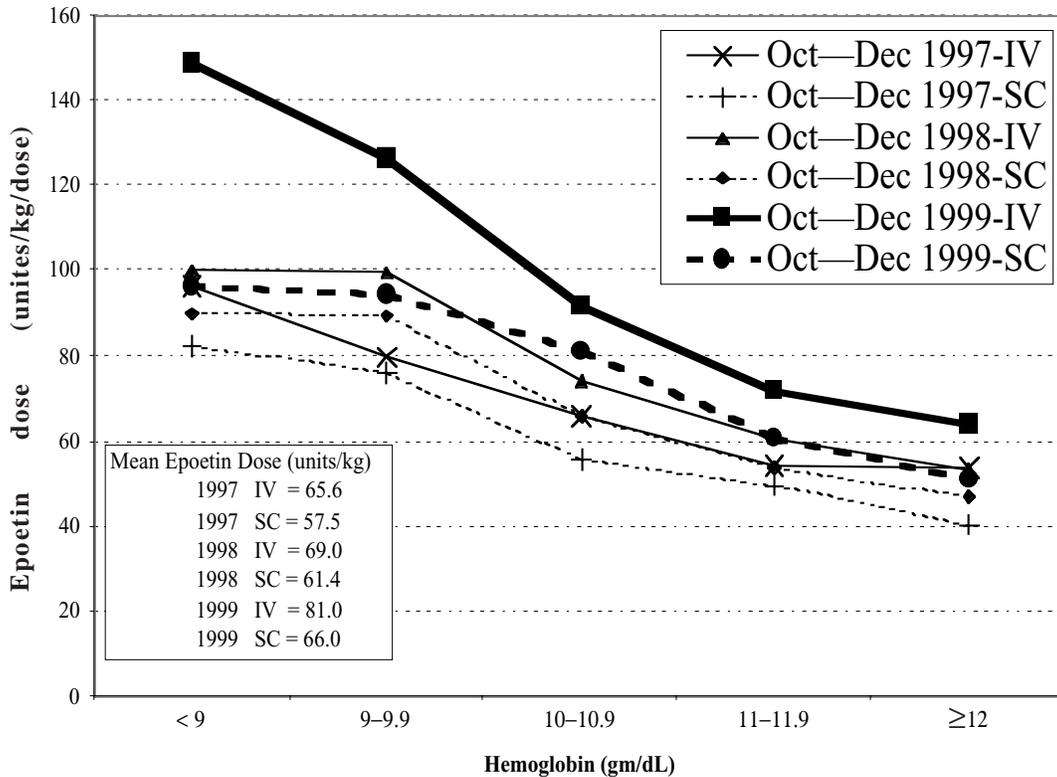
**Figure 27:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean hemoglobin values  $\geq 11$  gm/dL, by race, October–December 1999 compared to October–December 1997 and 1998. 2000 ESRD CPM Project.



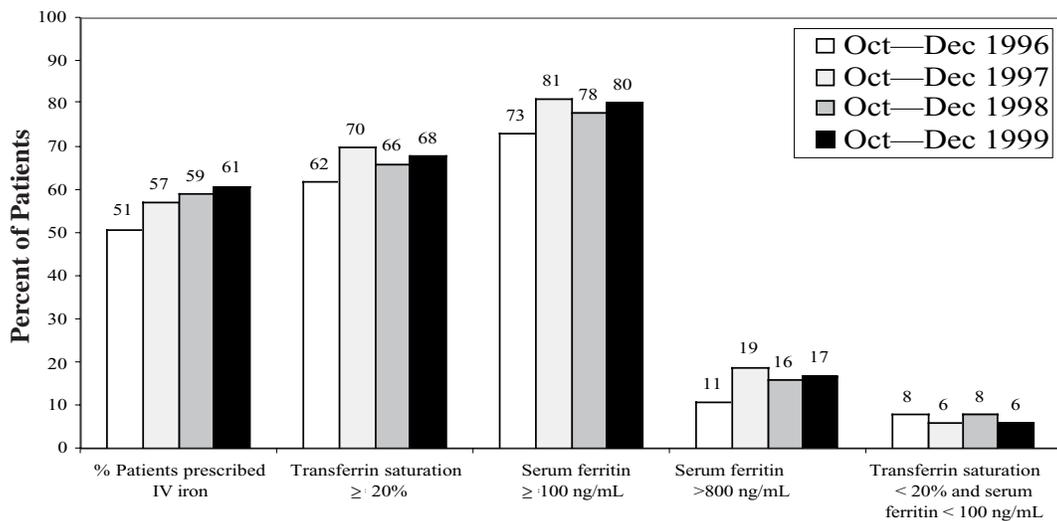
**Figure 28:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients who were prescribed Epoetin by hemoglobin category, October–December 1999 compared to October–December 1997 and 1998. 2000 ESRD CPM Project.



**Figure 29:** Mean prescribed Epoetin dose (units/kg/dose) for adult (aged  $\geq 18$  years) in-center hemodialysis patients, by hemoglobin category and route of administration, October–December 1999 compared to October–December 1997 and 1998. 2000 ESRD CPM Project.



**Figure 30:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients prescribed intravenous iron, with mean transferrin saturation  $\geq 20\%$ , mean serum ferritin concentration  $\geq 100$  ng/mL and  $> 800$  ng/mL, and with both mean transferrin saturation  $< 20\%$  and mean serum ferritin concentration  $< 100$  ng/mL, October–December 1999 compared to October–December 1996, 1997, and 1998. 2000 ESRD CPM Project.



## D. SERUM ALBUMIN

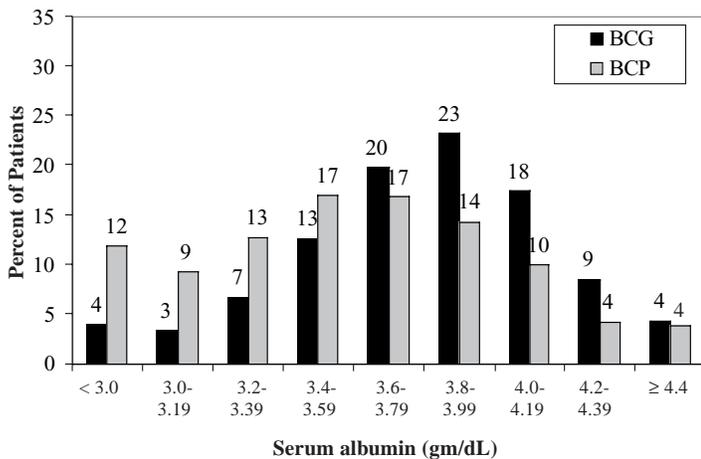
### 1. Findings for October–December 1999

The two commonly used laboratory methods for determining serum albumin values, bromocresol green (BCG) and bromocresol purple (BCP), have been reported to yield systematically different results (20). 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 serum albumin value for patients whose value was determined by the BCG method (n=7000) was 3.8 gm/dL, and by the BCP method (n=980) was 3.5 gm/dL.

Mean serum albumin < 3.5 gm/dL by the BCG method has been shown to be a marker for diminished survival (27-29). Since the percent of mean serum albumin < 3.2 gm/dL by the BCP method was nearly the same as the percent of serum albumin values < 3.5 gm/dL by the BCG method, we also defined a mean BCP result < 3.2 gm/dL as an indicator of inadequate serum albumin. "Optimal" serum albumin was defined as  $\geq 4.0$  gm/dL by the BCG method or  $\geq 3.7$  gm/dL by the BCP method. Figure 31 displays the distribution of serum albumin values by laboratory method.

**Figure 31:** Distribution of mean serum albumin for adult (aged  $\geq 18$  years) in-center hemodialysis patients, by laboratory method, October–December 1999. 2000 ESRD CPM Project.



\* Laboratory method: BCG = bromocresol green, BCP = bromocresol purple

The percent of patients with mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP) and  $\geq 4.0/3.7$  gm/dL (BCG/BCP) by gender, race, ethnicity, age, diagnosis groups, and duration of dialysis are shown in Table 14. A higher percent of men, Blacks, Hispanics, patients 18-44 years old, non-diabetics, and patients dialyzing six months or longer had a mean serum albumin  $\geq 4.0/3.7$  gm/dL (BCG/BCP) compared to women, Whites, non-Hispanics, patients older than 44 years, diabetics, and patients dialyzing less than six months.

**TABLE 14:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean serum albumin values  $\geq 3.5/3.2$  gm/dL (BCG/BCP)\* and  $\geq 4.0/3.7$  gm/dL (BCG/BCP) in the US, by patient characteristics, October-December 1999. 2000 ESRD CPM Project.

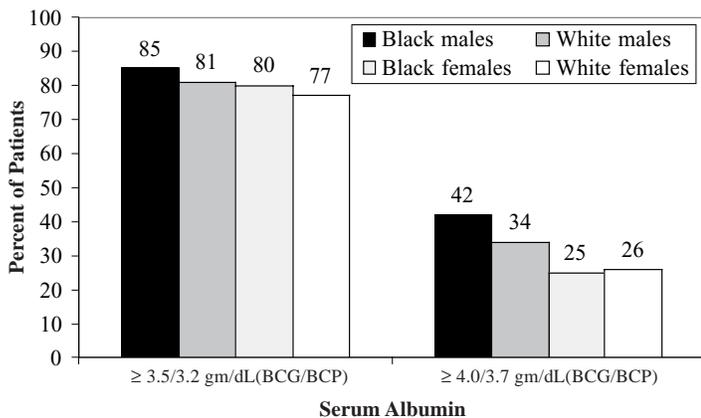
Patient Characteristic	SERUM ALBUMIN	
	% $\geq 3.5/3.2$ gm/dL	% $\geq 4.0/3.7$ gm/dL
<b>TOTAL</b>	<b>80</b>	<b>32</b>
<b>GENDER</b>		
Men	82	37
Women	78	26
<b>RACE</b>		
American Indian/ Alaska Native	73	19
Asian/Pacific Islander	82	37
Black	82	34
White	79	30
Other/Unknown	82	36
<b>ETHNICITY</b>		
Hispanic	83	37
Non-Hispanic	80	31
<b>AGE GROUP (years)</b>		
18-44	85	45
45-54	83	37
55-64	79	31
65-74	79	27
75+	78	23
<b>DIAGNOSIS</b>		
Diabetes mellitus	76	24
Hypertension	83	37
Glomerulonephritis	87	42
Other/Unknown	81	34
<b>DURATION of DIALYSIS (years)</b>		
< 0.5	59	18
0.5-0.9	77	27
1.0-1.9	83	33
2.0+	85	36

\* Note: Laboratory methods: BCG = bromocresol green; BCP = bromocresol purple

Nationally, 80% of patients had mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP) ranging from 75% to 86% among the 18 Networks; 32% of patients had mean serum albumin  $\geq 4.0/3.7$  gm/dL (BCG/BCP) ranging from 27% to 38% among the 18 Networks. The percent of patients in each Network area, by race, gender and age group, with mean serum albumin  $\geq 4.0/3.7$  gm/dL (BCG/BCP) is shown in Table 15.

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 32, TABLE 15). A higher percentage of non-diabetics achieved on average an “optimal” serum albumin over the three month study period compared to diabetic patients (37% vs. 24% respectively). Only 18% of patients dialyzing less than six months achieved an “optimal” serum albumin compared to 36% of patients dialyzing two or more years.

**Figure 32:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP) and  $\geq 4.0/3.7$  gm/dL (BCG/BCP), by race and gender, October–December 1999. 2000 ESRD CPM Project.



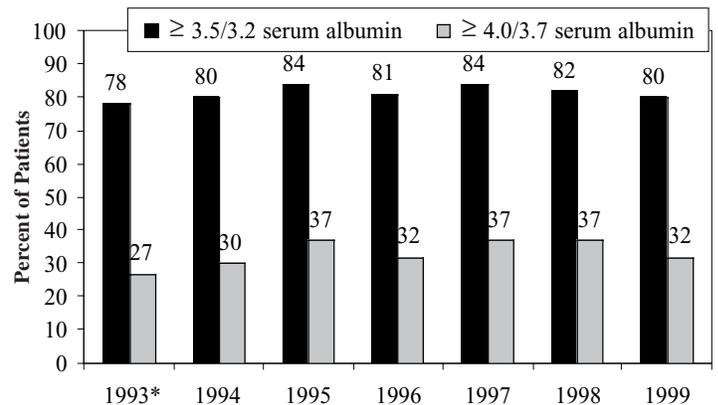
\*Note: BCG = bromcresol green laboratory method  
BCP = bromcresol purple laboratory method

## 2. Findings for October–December 1999 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 1999 compared to previous study periods.

Figure 33 shows the percent of patients with mean serum albumin  $\geq 3.5$  gm/dL (BCG) or  $\geq 3.2$  gm/dL (BCP) and the percent of patients with mean serum albumin values  $\geq 4.0$  gm/dL (BCG) or  $\geq 3.7$  gm/dL (BCP) during October–December 1999 compared to October–December 1993 through 1998.

**Figure 33:** Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP) and  $\geq 4.0/3.7$  gm/dL (BCG/BCP), October–December 1999 compared to October–December 1993, 1994, 1995, 1996, 1997, and 1998. 2000 ESRD CPM Project.



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

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

**TABLE 15: Percent of adult (aged  $\geq 18$  years) in-center hemodialysis patients with mean serum albumin  $\geq 4.0$  gm/dL (BCG method) or  $\geq 3.7$  gm/dL (BCP method), by race, gender, age, and Network, October-December 1999. 2000 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	34	37	32	28	28	33	28	33	31	31	32	32	31	30	33	27	38	31	32	
RACE																				
Black	33	38	34	29	32	37	30	35	37	34	28	31	35	31	32	30	38	26	34	
White	34	36	31	29	23	24	25	31	27	29	34	32	26	29	33	27	38	33	30	
GENDER																				
Men	37	43	36	35	35	38	30	41	37	35	34	35	37	37	40	30	42	38	37	
Women	30	29	27	21	21	28	24	26	25	27	30	27	25	22	25	23	33	25	26	
AGE GROUP (years)																				
18-44	41	57	46	43	36	56	34	51	47	31	41	47	45	37	46	44	53	46	45	
45-54	40	42	34	45	33	39	32	35	35	44	32	41	39	35	24	29	47	37	37	
55-64	36	34	30	23	28	32	30	40	21	37	35	21	26	33	33	35	35	28	31	
65-74	33	28	30	22	25	29	25	26	29	24	35	25	19	21	33	16	36	24	27	
75+	27	28	25	21	21	16	19	17	24	23	22	27	25	23	28	19	25	24	23	

## PERITONEAL DIALYSIS PATIENTS

### 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 2000 project were:

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

**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, 1999, was selected (sample size 1,735).

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 1999–March 2000 for aggregation. This aggregated data file was then forwarded to HCFA for initial analysis.

- Initial Findings: The sample for analysis consisted of 1,603 patients, which was 92% of the original sample. Highlights from the initial findings are summarized below.

### IMPROVEMENT OCCURRED

- Adequacy of dialysis was assessed at least once for approximately 85% of the sampled patients during the 2000 study period (October 1999–March 2000), compared to 85% during the 1999 study period (October 1998–March 1999) and 81% during the 1998 study period (November 1997–April 1998) (FIGURE 34).

- 65% of CAPD patients had a mean weekly  $Kt/V_{urea}$  meeting NKF-DOQI guidelines during the 2000 study period compared to 56% during the 1999 study period.

61% of CAPD patients had a mean weekly creatinine clearance (CrCl) meeting these guidelines during the 2000 study period compared to 51% during the 1999 study period. A similar improvement was noted for cycler patients (60% compared to 52% for weekly  $Kt/V_{urea}$  and 51% compared to 43% for weekly CrCl during the 2000 study period compared to the 1999 study period, respectively). (FIGURES 6, 7, TABLE 16).

- An improvement of 7 percentage points occurred in the percent of peritoneal dialysis patients with mean hemoglobin  $\geq 11$  gm/dL from the 1999 study period (62%) to the 2000 study period (69%).

### OPPORTUNITIES TO IMPROVE

- The adequacy of dialysis was not assessed during the 2000 study period for an estimated 15% of the sampled peritoneal dialysis patients.

- 35% of CAPD patients did not meet an adequate weekly  $Kt/V_{urea}$  and 39% did not meet an adequate weekly CrCl. Likewise, 40% of cycler patients did not meet an adequate weekly  $Kt/V_{urea}$  and 49% did not meet an adequate weekly CrCl.

- 42% of peritoneal dialysis patients who met the inclusion criteria prescribed Epoetin did not have a mean hemoglobin 11–12.9 gm/dL in the 2000 study period.

- 44% of peritoneal dialysis patients did not have mean serum albumin  $\geq 3.5$  gm/dL (BCG method) or  $\geq 3.2$  gm/dL (BCP method) in the 2000 study period.

- 83% of peritoneal dialysis patients did not have mean serum albumin  $\geq 4.0$  gm/dL (BCG method) or  $\geq 3.7$  gm/dL (BCP method) in the 2000 study period.

### NEXT STEPS:

Network and HCFA staff will work with ESRD facility staff to carry out intervention activities to improve care for ESRD patients in 2001, 2002 and beyond. Recently, HCFA implemented a web site entitled "Dialysis Facility Compare" which can be found at [www.medicare.gov](http://www.medicare.gov). This site provides dialysis facility-specific information to the public in an effort to assist ESRD patients and families in becoming informed consumers.

## IV. PERITONEAL DIALYSIS PATIENTS

This section describes the findings for adult peritoneal dialysis patients for selected CPMs and other quality indicators related to adequacy of 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 1999–March 2000 (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 1999–March 2000 and previous study periods. A national random sample of adult ( $\geq 18$  years) peritoneal dialysis patients who were alive on December 31, 1999, was selected (sample size=1735). 1603 patients (92%) were included in the sample for analysis.

### A. ADEQUACY OF PERITONEAL DIALYSIS

#### 1. CPM Findings for October 1999–March 2000

Data to assess three peritoneal dialysis adequacy CPMs were collected in 2000. The time period from which these data were abstracted was October 1999–March 2000. Tidal peritoneal dialysis patients (n=24) 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:** 83% 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:** 59% 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 calculated ( $Kt/V_{urea}$  and creatinine clearance) 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 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For NIPD patients (cycler patients without a daytime dwell),

the delivered peritoneal dialysis dose is a weekly  $Kt/V_{urea}$  of at least 2.2 and a weekly creatinine clearance of at least 66 L/week/1.73 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

For CCPD patients (cycler patients with a daytime dwell), the delivered peritoneal dialysis dose is a weekly  $Kt/V_{urea}$  of at least 2.1 and a weekly creatinine clearance of at least 63 L/week/1.73 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

**FINDING:** 68% of CAPD patients had a mean weekly  $Kt/V_{urea} \geq 2.0$  and a mean weekly creatinine clearance  $\geq 60$  L/week/1.73 m<sup>2</sup> OR there was evidence the dialysis prescription was changed if the adequacy measurements were below these thresholds during the six-month study period.

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

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

#### 2. Other Peritoneal Dialysis Adequacy Findings for October 1999–March 2000

Tidal peritoneal dialysis patients (n=24) were excluded from the adequacy analyses reported below. By using values that were abstracted from medical records of peritoneal dialysis patients, it was possible to calculate at least one of the adequacy measures (weekly  $Kt/V_{urea}$  or weekly creatinine clearance) for 1,299 (82%) of the 1,579 patients included for these analyses during the 2000 study period.

Of the 280 (18%) medical records with insufficient information to calculate an adequacy measure, 51 (18%) had at least either one weekly  $Kt/V_{urea}$  value (51 records) or one weekly creatinine clearance value (43 records) recorded during the 2000 study period. Approximately 85% of peritoneal dialysis patients had adequacy of dialysis assessed at least once during this study period.

65% of CAPD and 60% of cycler patients had a mean calculated weekly  $Kt/V_{urea}$  that met recommended NKF DOQI guidelines; 61% of CAPD and 51% of cycler patients had a mean calculated weekly creatinine clearance that met recommended NKF DOQI guidelines (TABLE 16).

**TABLE 16:** Percent of adult (aged ≥ 18 years) peritoneal dialysis patients with mean ( ± SD) weekly adequacy values meeting NKF DOQI guidelines, and median adequacy values, October 1999–March 2000 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.

	Nov 94–Apr 95*	Nov 95–Apr 96	Nov 96–Apr 97	Nov 97–Apr 98	Oct 98–Mar 99	Oct 99–Mar 00					
<b>Adequacy Measure</b>	<b>CAPD (n=951)</b>	<b>CAPD (n=796)</b>	<b>Cyclers (n=402)</b>	<b>CAPD (n=757)</b>	<b>Cyclers (n=521)</b>	<b>CAPD (n=804)</b>	<b>Cyclers (n=663)</b>	<b>CAPD (n=762)</b>	<b>Cyclers<sup>†</sup> (n=626)</b>	<b>CAPD (n=646)</b>	<b>Cyclers<sup>††</sup> (n=745)</b>
<b>Weekly Kt/V urea</b>											
% meeting NKF DOQI <sup>^</sup>	23	27	28	36	36	45	42	56	52	65	60
mean ( ± SD)	1.91 (±0.8)	2.00 (±0.6)	2.12 (±0.6)	2.12 (±0.6)	2.24 (±0.6)	2.20 (±0.6)	2.25 (±0.6)	2.22 (±0.5)	2.31 (±0.6)	2.27 (±0.6)	2.34 (±0.6)
median	1.90	1.90	2.00	2.00	2.20	2.10	2.20	2.20	2.30	2.20	2.20
<b>Weekly Creatinine Clearance</b>											
% meeting NKF DOQI	21	30	26	34	33	41	32	51	43	61	51
mean ( ± SD)	61.5 (±31.6)	64.3 (±23.6)	63.4 (±23.5)	65.8 (±24.7)	67.4 (±24.4)	67.8 (±22.6)	66.5 (±22.0)	70.4 (±25.2)	69.1 (±23.7)	72.7 (±24.9)	71.6 (±25.1)
median	57.2	59.6	59.0	60.7	62.2	63.0	60.8	64.9	63.6	65.9	65.5

<sup>^</sup> NKF DOQI guidelines:

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

For cyclers patients with daytime dwell:  $Kt/V_{urea} \geq 2.1$ ; creatinine clearance  $\geq 63$  L/week/1.73m<sup>2</sup>

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

\* Data for cycler patients November 1994–April 1995 not shown due to low number of cycler patients during that study period.

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

<sup>††</sup> Tidal peritoneal dialysis patients were excluded from these analyses (n=24).

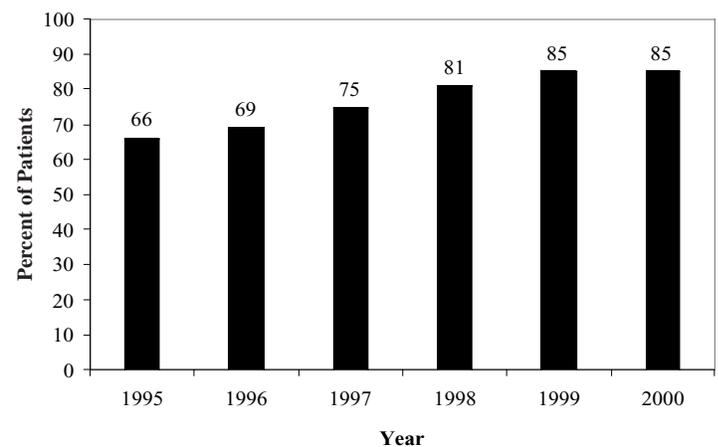
### 3. CPM and Other Findings for October 1999–March 2000 compared to previous study periods

The adequacy of dialysis was assessed for approximately 85% of adult peritoneal dialysis patients at least once during the 2000 six-month study period (October 1999–March 2000), compared to only 66% during the 1995 study period, 69% during the 1996 study period, 75% during the 1997 study period, 81% during the 1998 study period, and 85% during the 1999 study period (FIGURE 34).

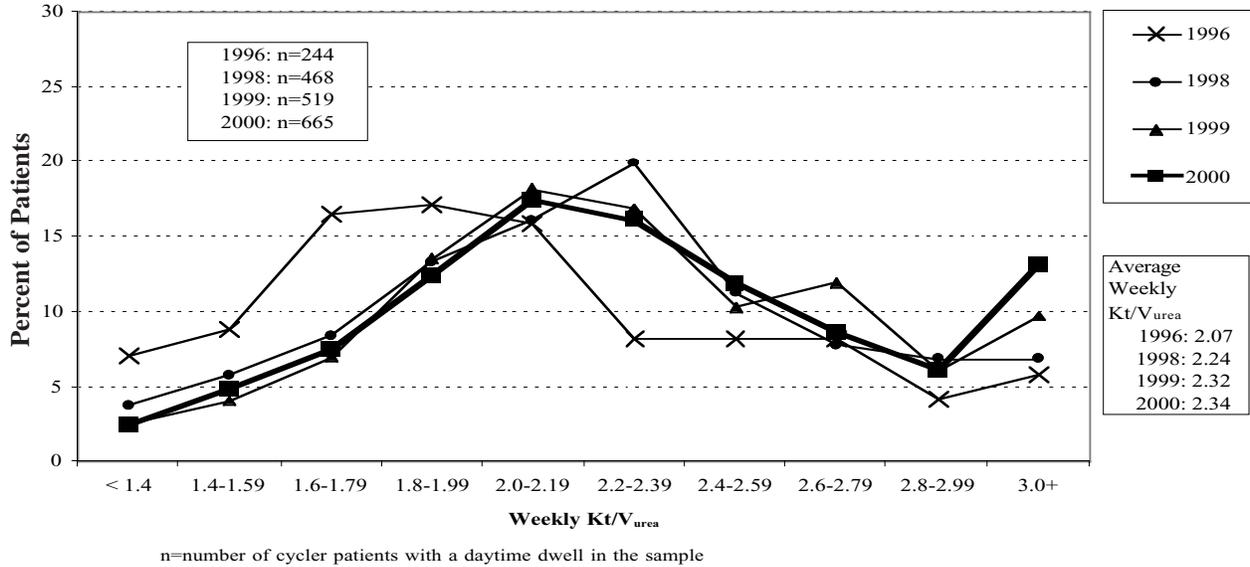
In addition to increasing numbers of patients having an adequacy measure performed during the six-month study period, both CAPD and cycler patients have experienced improved clearances from November 1994–April 1995 to October 1999–March 2000 (TABLE 16).

Figures 35 and 36 depict the improvement in the delivered adequacy of dialysis for cycler patients with a daytime dwell (CCPD patients) from the 1996–2000 study periods. Mean weekly  $Kt/V_{urea}$  and weekly creatinine clearance values for all cycler patients increased over this time period (TABLE 16). A similar improvement in adequacy measures occurred for CAPD patients (FIGURES 6, 7, TABLE 16).

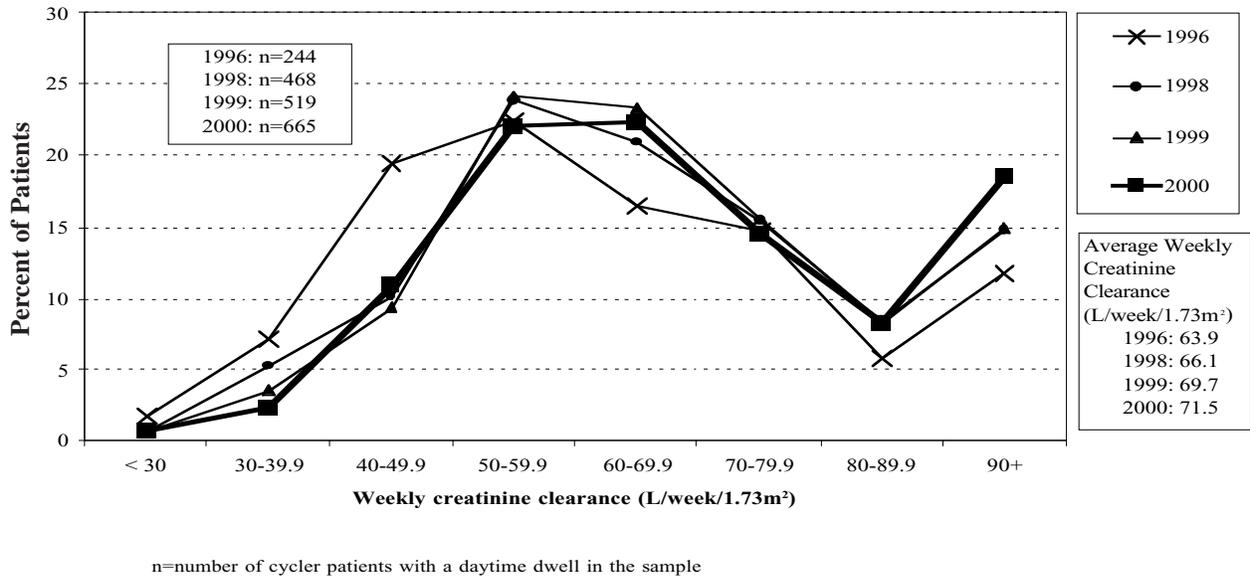
**Figure 34:** Estimated percent of adult (aged ≥ 18 years) peritoneal dialysis patients with at least one adequacy assessment October 1999–March 2000, compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.



**Figure 35:** Distribution of mean weekly  $Kt/V_{urea}$  for adult (aged  $\geq 18$  years) cycler patients with a daytime dwell, October 1999–March 2000 compared to November 1995–April 1996, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.



**Figure 36:** Distribution of mean weekly creatinine clearance ( $L/week/1.73m^2$ ) for adult (aged  $\geq 18$  years) cycler patients with a daytime dwell, October 1999–March 2000 compared to November 1995–April 1996, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.



## B. ANEMIA MANAGEMENT

### 1. CPM Findings for October 1999–March 2000

Data to assess three anemia management CPMs were collected in 2000. The time period from which these data were abstracted was October 1999–March 2000.

**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, 58% of the peritoneal dialysis patients who met the inclusion criteria (n=1468) had a mean hemoglobin 11–12.9 gm/dL.

**Anemia Management CPM IIa** — 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:** 68% of the peritoneal dialysis patients who met the inclusion criteria (n=1462) had at least two documented (measured) transferrin saturation values and at least two documented (measured) serum ferritin concentration values during October 1999–March 2000.

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

**FINDING:** 70% of the adult peritoneal dialysis patients who met the inclusion criteria (n=1462) had at least one documented transferrin saturation  $\geq$  20% and at least one documented serum ferritin concentration  $\geq$  100 ng/mL during October 1999–March 2000.

**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  $\geq$  50% or the mean serum ferritin concentration was  $\geq$  800 ng/ml; UNLESS the patient was in the first three months of dialysis and was prescribed a trial dose of oral iron.

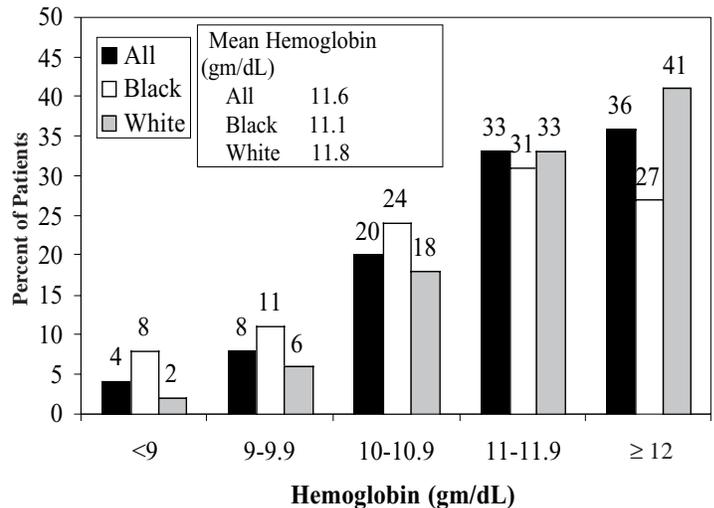
**FINDING:** 18% of the peritoneal dialysis patients who met the inclusion criteria (n=598) were prescribed intravenous iron in at least one month during October 1999–March 2000.

### 2. Other Anemia Management Findings for October 1999–March 2000

The average hemoglobin for adult peritoneal dialysis patients in the sample was 11.6 gm/dL. The distributions of mean hemoglobin values for Black and White patients are depicted in Figure 37. 69% of patients had a mean hemoglobin  $\geq$  11 gm/dL. Significantly more men, Whites, and patients older than 45 years had a mean hemoglobin  $\geq$  11 gm/dL compared to women, Blacks, and younger patients (TABLE 17). Nationally, 58% of patients prescribed Epoetin had a mean hemoglobin 11–12.9 gm/dL.

The mean hemoglobin values and the proportion of patients within different hemoglobin categories for gender, race, ethnicity, age, diagnosis, and duration of dialysis are shown in Table 17. The prevalence of patients with mean hemoglobin < 9 gm/dL was 4%. The prevalence of patients with mean hemoglobin < 10 gm/dL was 11%. The prevalence of patients with mean hemoglobin < 10 gm/dL was significantly higher in Blacks compared to Whites and for patients 18–44 years old compared to older patients (TABLE 17).

**Figure 37:** Distribution of mean hemoglobin values for adult (aged  $\geq$  18 years) peritoneal dialysis patients in the US, by race, October 1999–March 2000. 2000 ESRD CPM Project.



Note: The values appearing above the bars in the graph have been rounded.

**TABLE 17:** Mean hemoglobin values (gm/dL) for adult (aged ≥ 18 years) peritoneal dialysis patients, by patient characteristics, October 1999-March 2000. 2000 ESRD CPM Project.

Patient Characteristic	Mean Hemoglobin (gm/dL)	Percent of patients with hemoglobin values (gm/dL)				
		< 9	9-9.9	10-10.9	11-11.9	≥ 12
<b>TOTAL</b>	<b>11.6</b>	<b>4</b>	<b>7</b>	<b>20</b>	<b>33</b>	<b>36</b>
<b>GENDER</b>						
Men	11.8	3	7	15	33	42
Women	11.4	4	8	24	33	30
<b>RACE</b>						
American Indian/ Alaska Native	11.4	6	11	11	33	39
Asian/Pacific Islander	11.6	4	6	17	32	41
Black	11.1	8	11	24	31	27
White	11.8	2	6	18	33	41
Other/Unknown	11.3	3	7	17	49	23
<b>ETHNICITY</b>						
Hispanic	11.7	2	6	19	37	36
Non-Hispanic	11.5	4	8	20	33	36
<b>AGE GROUP (years)</b>						
18-44	11.3	7	11	24	27	31
45-54	11.6	4	9	18	34	35
55-64	11.6	3	5	19	37	36
65-74	11.8	2	6	16	34	42
75+	11.9	0	1	18	38	44
<b>DIAGNOSIS</b>						
Diabetes Mellitus	11.6	3	7	20	35	36
Hypertension	11.4	4	10	19	33	34
Glomerulonephritis	11.5	3	9	22	34	33
Other/Unknown	11.7	6	5	17	31	41
<b>DURATION of DIALYSIS (years)</b>						
< 0.5	11.8	2	8	16	34	40
0.5-0.9	11.6	3	8	19	34	37
1.0-1.9	11.6	3	6	18	35	37
2.0+	11.5	5	8	22	32	34

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

The average transferrin saturation for the patients in this sample was 28.8%, and 74% of patients had mean transferrin saturation ≥ 20%. The average serum ferritin concentration for this population was 399 ng/mL, with 76% of patients having a mean serum ferritin concentration ≥ 100 ng/mL. 114 patients (7% of patients) had both a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

Because patients could have Epoetin prescribed during one month but not during another, we were not able to correlate Epoetin use with the mean hemoglobin values. Instead, we assessed Epoetin use at the time of each of the 4440 hemoglobin determinations reported for this study period. Overall, Epoetin was prescribed 89% of the time when a hemoglobin was determined. Epoetin was prescribed 98% of the time when the hemoglobin values were < 9 gm/dL, 94% 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, 96% of the time when the hemoglobin values were between 11-11.9 gm/dL, and 77% of the time when hemoglobin values were ≥ 12 gm/dL.

The prescribed route of administration of Epoetin was collected for the first time this study period. Within the subset of patients who were prescribed Epoetin, 98% were prescribed Epoetin by the subcutaneous route; 3% were prescribed Epoetin by the intravenous route (groups not mutually exclusive).

Iron use was assessed during this study period. Iron by either the oral or intravenous route was prescribed at least once during the six months for 74% of the patients in this sample, and throughout the six-month period for 53% of the patients. Of the patients prescribed iron, 89% were prescribed oral iron and 19% were prescribed intravenous iron (not mutually exclusive categories). Among those patients with mean transferrin saturation < 20% and mean serum ferritin concentration < 100 ng/mL (n=114), 86% were prescribed either oral or IV iron at least once during the six months, and 63% received some iron all six months. 16% of these patients were prescribed IV iron at least once during the six-month study period.

### 3. CPM and Other Findings for October 1999–March 2000 compared to previous study periods

The average hemoglobin increased from 11.4 gm/dL during the 1999 study period to 11.6 gm/dL during the 2000 study period (FIGURE 8). The distributions of mean hemoglobin values over these three study periods were not significantly different by modality (CAPD vs. cycler). The percent of peritoneal dialysis patients with mean hemoglobin ≥ 11 gm/dL increased from 55% to 69% from the 1998 to the 2000 study periods. This improvement was noted for both Black patients (from 38% to 58%) and for White patients (63% to 74%).

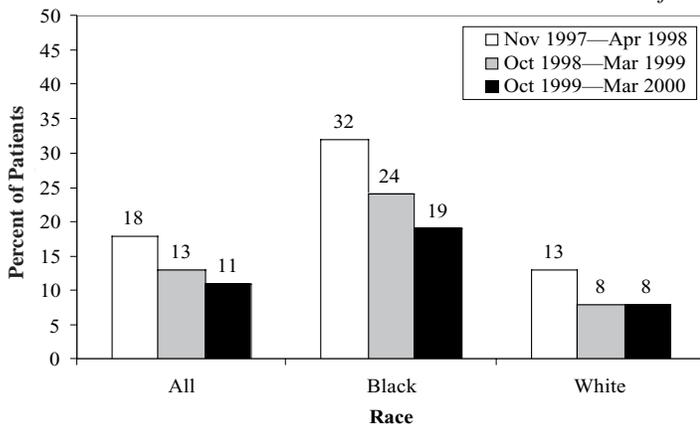
The percent of adult (aged  $\geq 18$  years) peritoneal dialysis patients with mean hemoglobin  $< 10$  gm/dL decreased from 18% in the 1998 study period to 11% in the 2000 study period (FIGURE 38).

The distributions of mean transferrin saturation values (%) and mean serum ferritin concentrations (ng/mL) were similar for the November 1996–April 1997, November 1997–April 1998, October 1998–March 1999, and October 1999–March 2000 study periods (FIGURES 39, 40).

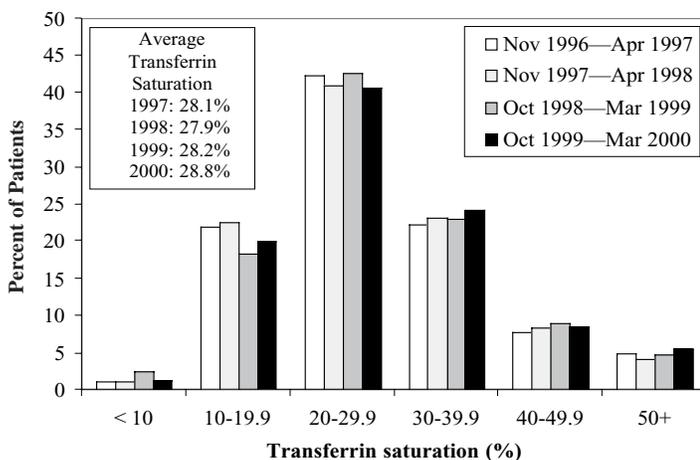
Figure 41 depicts the trend in Epoetin dosing from the 1998 study period to the 2000 study period, with an increasing mean Epoetin dose (units/kg/dose) for patients prescribed Epoetin in most hemoglobin categories from the 1998 to the 2000 study periods. Route of administration information for the 2000 study period revealed that IV doses were generally larger than SC doses.

Figure 42 shows the percent of patients prescribed Epoetin by hemoglobin category for study periods 1998 through 2000.

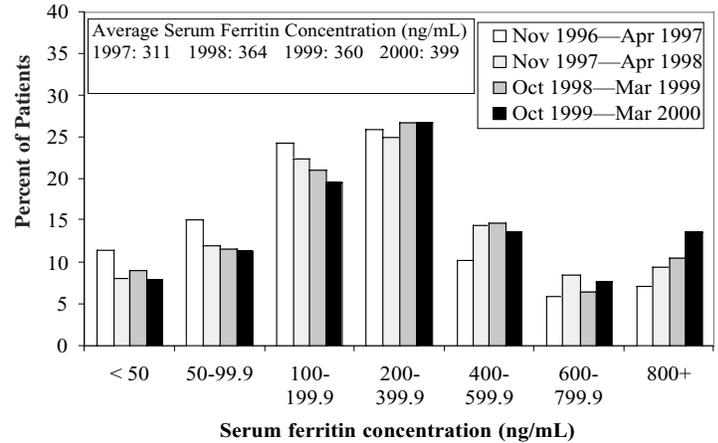
**Figure 38:** Percent of adult (aged  $\geq 18$  years) peritoneal dialysis patients with mean hemoglobin  $< 10$  gm/dL, by race, October 1999–March 2000 compared to November 1997–April 1998 and October 1998–March 1999. 2000 ESRD CPM Project



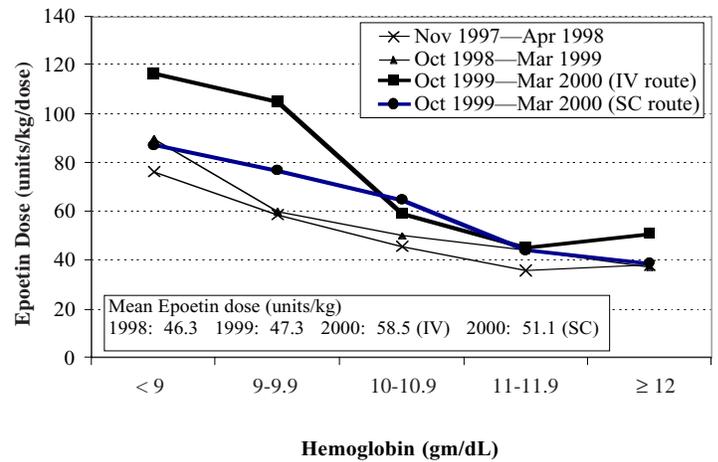
**Figure 39:** Distribution of mean transferrin saturation values (%) for adult (aged  $\geq 18$  years) peritoneal dialysis patients, October 1999–March 2000 compared to November 1996–April 1997, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.



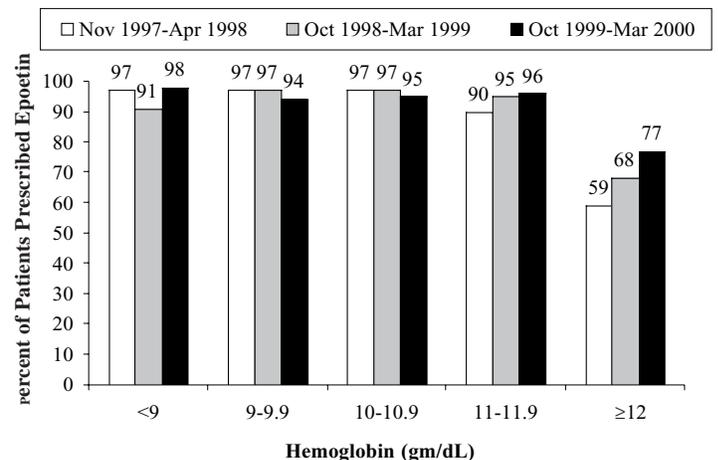
**Figure 40:** Distribution of mean serum ferritin concentration (ng/mL) for adult (aged  $\geq 18$  years) peritoneal dialysis patients, October 1999–March 2000 compared to November 1996–April 1997, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.



**Figure 41:** Mean Epoetin dose (units/kg/dose) by hemoglobin category for adult (aged  $\geq 18$  years) peritoneal dialysis patients prescribed Epoetin October 1999–March 2000 compared to November 1997–April 1998 and October 1998–March 1999. 2000 ESRD CPM Project.



**Figure 42:** Percent of adult (aged  $\geq 18$  years) peritoneal dialysis patients who were prescribed Epoetin by hemoglobin category, October 1999–March 2000 compared to November 1997–April 1998 and October 1998–March 1999. 2000 ESRD CPM Project.



## C. SERUM ALBUMIN

### 1. Findings for October 1999–March 2000

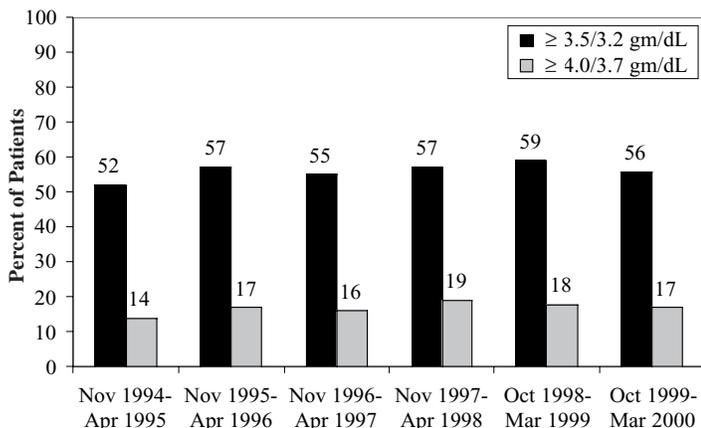
The mean serum albumin value for peritoneal dialysis patients whose value was determined by the BCG method (n=1,405) was 3.5 gm/dL and by the BCP method (n=181) was 3.3 gm/dL. “Adequate” serum albumin was defined for this report as  $\geq 3.5$  gm/dL (BCG) or  $\geq 3.2$  gm/dL (BCP). “Optimal” serum albumin was defined as  $\geq 4.0$  gm/dL (BCG) or  $\geq 3.7$  gm/dL (BCP). Nationally, 56% of patients had a mean serum albumin  $\geq 3.5$  gm/dL by the BCG or  $\geq 3.2$  gm/dL by the BCP method. 17% of patients had a mean serum albumin  $\geq 4.0$  (BCG) or  $\geq 3.7$  gm/dL (BCP). The percent of patients with mean serum albumin defined as either “adequate” or “optimal” by gender, race, ethnicity, age, diagnosis, and duration of dialysis is shown in Table 18. 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, and for non-diabetics compared to diabetics (TABLE 18).

### 2. Findings for October 1999–March 2000 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 2000 study period.

Figure 43 shows the percent of patients with mean serum albumin  $\geq 3.5$  gm/dL (BCG) method or  $\geq 3.2$  gm/dL (BCP) method and the percent of patients with mean serum albumin  $\geq 4.0$  (BCG) method or  $\geq 3.7$  gm/dL (BCP) method during the 2000 study period compared to the 1995, 1996, 1997, 1998, and 1999 study periods.

**Figure 43:** Percent of adult (aged  $\geq 18$  years) peritoneal dialysis patients with mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP) and  $\geq 4.0/3.7$  gm/dL (BCG/BCP), October 1999–March 2000 compared to November 1994–April 1995, November 1995–April 1996, November 1996–April 1997, November 1997–April 1998, and October 1998–March 1999. 2000 ESRD CPM Project.



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

**TABLE 18:** Percent of adult (aged  $\geq 18$  years) peritoneal dialysis patients with mean serum albumin values  $\geq 3.5/3.2$  gm/dL (BCG/BCP)\* and  $\geq 4.0/3.7$  gm/dL (BCG/BCP) in the US, by patient characteristics, October 1999-March 2000. 2000 ESRD CPM Project.

Patient Characteristic	ALBUMIN	
	$\geq 3.5/3.2$ gm/dL	$\geq 4.0/3.7$ gm/dL
<b>TOTAL</b>	<b>56</b>	<b>17</b>
<b>GENDER</b>		
Men	61	20
Women	52	13
<b>RACE</b>		
American Indian/ Alaska Native	67	22
Asian/Pacific Islander	69	20
Black	52	13
White	56	18
Other/Unknown	75	22
<b>ETHNICITY</b>		
Hispanic	62	18
Non-Hispanic	56	16
<b>AGE GROUP (years)</b>		
18-44	64	27
45-54	62	20
55-64	56	14
65-74	48	8
75+	42	7
<b>DIAGNOSIS</b>		
Diabetes mellitus	50	12
Hypertension	57	17
Glomerulonephritis	59	21
Other/Unknown	64	21
<b>DURATION OF DIALYSIS (years)</b>		
< 0.5	63	21
0.5-0.9	59	16
1.0-1.9	54	17
2.0+	53	16

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