

A COMPARISON OF INTERMEDIATE OUTCOMES FOR ADULT PERITONEAL DIALYSIS PATIENTS IN THE U.S. BY DIABETES MELLITUS AS THE CAUSE OF ESRD VS. OTHER CAUSES OF ESRD: RESULTS FROM THE 2001 END STAGE RENAL DISEASE (ESRD) CLINICAL PERFORMANCE MEASURES PROJECT.

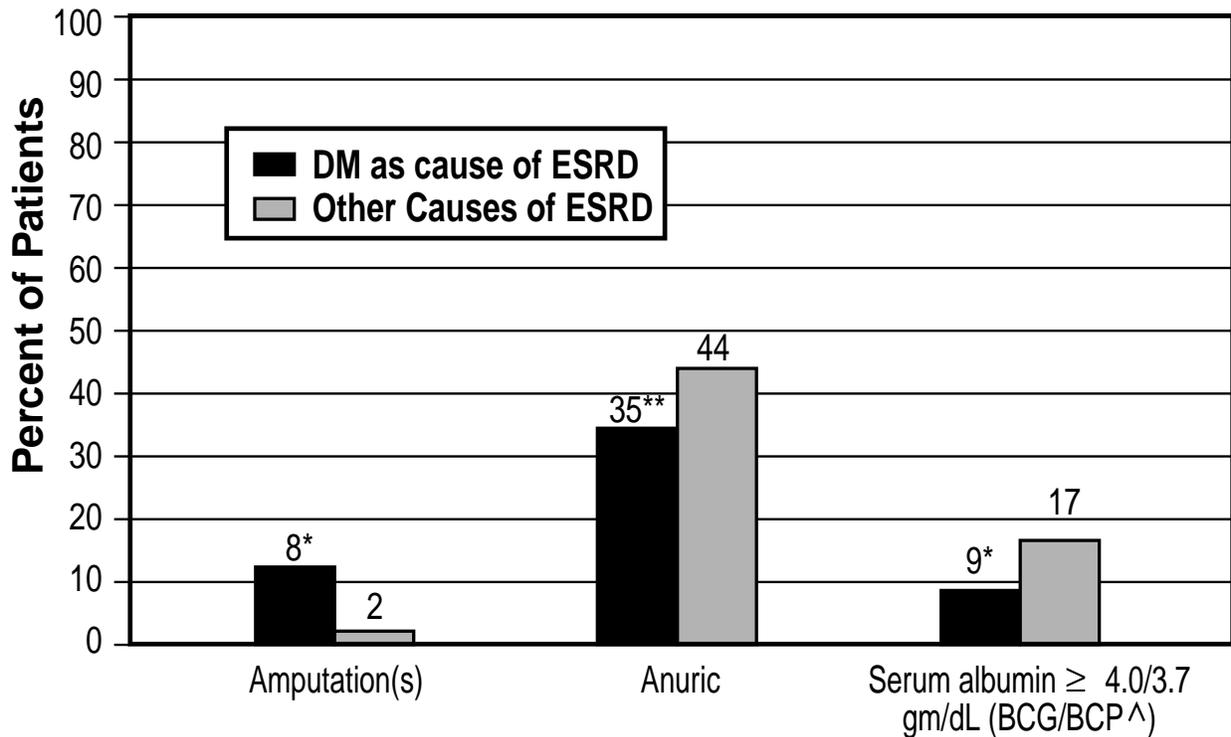
Supplemental Report #5

2001 ESRD Clinical Performance Measures Project

The Centers for Medicare & Medicaid Services

April 2002

*Significant Findings for Adult Peritoneal Dialysis Patients in the U.S.,
by Diabetes Mellitus as the Cause of ESRD vs. Other Causes of ESRD,
October 2000 -March 2001*



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

Significant difference noted by: * p < 0.001; ** p < 0.01



INTRODUCTION

The purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in the assessment of care provided to ESRD patients and to stimulate improvement in that care. Annually, a national random sample of adult (aged ≥ 18 years) peritoneal dialysis (PD) patients is selected for inclusion in this Project. This report is divided into two sections: 1) a description of several intermediate outcomes of care and process measures for patients with diabetes mellitus as the primary cause of ESRD (DM+) compared to patients with other causes of ESRD combined; and 2) findings for the DM+ subset by gender, race, and body mass index (BMI) category.

The ESRD CPM Project did not collect data on DM as a comorbidity. The categorizations for this report reflect only the information reported for the primary cause of ESRD as reported on the Medical Evidence Form (HCFA-2728).

METHODS

The Sample

In March 2001, a listing of adult PD patients who were alive and dialyzing on December 31, 2000 was obtained from the 18 ESRD Network organizations. From this universe of patients, a national random sample was drawn. There were 1439 patients selected for the national sample.

Data Collection

During May 2001, a four-page data collection form was sent to each facility that had one or more patients selected for inclusion in the study. Clinical information in the patients' medical records was abstracted for each patient who was receiving PD during the months of October 2000 through March 2001. Patient characteristic information included: gender, age, race, Hispanic ethnicity, years on dialysis, primary cause of ESRD, and presence of any amputation(s). The parameters of care examined included adequacy of dialysis, management of anemia, and assessment of serum albumin.

Clinical information used to assess the quality of care provided to these patients included the following: patient height and weight, hemoglobin (Hgb) values, prescribed Epoetin dose and route of administration, iron use and route of administration, transferrin saturation values, serum ferritin concentrations, serum albumin values and the laboratory method used to determine these values (bromocresol green [BCG] and bromocresol purple [BCP] methods).

Completed forms were returned to the appropriate Network office where data were reviewed and entered into a computerized database (Visual FoxPro). The data were forwarded to the Centers for Medicare & Medicaid Services (CMS) for analysis.

Data Analysis

All available reported monthly values were utilized in calculating mean (\pm SD) and median values. The calculation of weekly Kt/V urea and creatinine clearance values was performed by standard methods, using data from 24 hour dialysate and urine collections. For Kt/V urea, residual renal function was calculated using urine urea clearance only. For creatinine clearance, residual renal function was calculated to be the average of the urine urea and creatinine clearances. The V was determined by the method of Watson,¹ and body surface area (BSA[m²]) was calculated using the formula by Dubois and Dubois.²

Associations by race were restricted to black and white races only due to the small numbers in other racial groups. Associations of clinical data with patient characteristics were tested by Chi square, hierarchical ANOVA, and two-tailed Student's t-test analyses, with a p-value < 0.05 considered to be significant. Analyses for this report were completed utilizing Epi Info v.6.04a³ and SPSS for Windows, v. 10.0.⁴

RESULTS

The Sample for Analysis

Of the 1439 patients selected for the sample, 1342 (93%) met the inclusion criteria for analysis. 1335/1342 (99.5%) of patients in the sample for analysis had a reported primary cause of ESRD. Selected characteristics of the patients in the sample for analysis are shown in Table 1. 36% of the patients had DM as the primary cause of ESRD. 60% of the DM+ group were white. There was a significantly larger percentage of older patients in the DM+ group. DM+ patients had a significantly shorter duration of dialysis therapy compared to patients with other causes of ESRD combined (1.7 yrs vs. 3.4 yrs, $p < 0.001$). DM+ patients had significantly higher mean BSA compared to patients with other causes of ESRD combined (1.88 vs. 1.84, $p < 0.01$). A significantly larger percentage of patients in the DM+ group had an amputation(s) compared to patients with other causes combined (8% vs. 2%, $p < 0.001$). 35% of DM+ patients were anuric compared to 44% of patients with other causes combined ($p < 0.01$).

Section I: Comparison of DM+ Patients to Patients with Other Causes of ESRD Combined

Adequacy of Dialysis

There was no significant difference in mean total, renal or peritoneal weekly Kt/V urea or percent of patients with a mean weekly Kt/V urea ≥ 2.0 for DM+ patients compared to patients with other causes combined (Table 2). The mean total weekly creatinine clearance was significantly higher for DM+ patients compared to patients with other causes combined (76.5 L/wk/1.73m² vs. 71.6 L/wk/1.73m², $p < 0.01$), as was the renal clearance (45.0 L/wk/1.73m² vs. 38.2 L/wk/1.73m², $p < 0.05$). There was no significant difference in peritoneal creatinine clearance between groups.

Table 1: Selected patient characteristics for adult PD patients, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Characteristic | DM as cause of ESRD n (%) | Other causes of ESRD combined n (%) |
|----------------------------------------------|---------------------------|-------------------------------------|
| TOTAL | 480 (100) | 855 (100) |
| Gender | | |
| Male | 236 (49) | 436 (51) |
| Female | 244 (51) | 419 (49) |
| Race | | |
| Black | 125 (26) | 242 (28) |
| White | 286 (60) | 520 (61) |
| Ethnicity | | |
| Hispanic | 62 (13) | 80 (9) |
| Non-Hispanic | 403 (84) | 739 (86) |
| Age (years)*** | | |
| Mean (\pm SD) | 57.1 (\pm 12.4) | 52.7 (\pm 15.8) |
| Median | 58.7 | 51.9 |
| 18-44 | 85 (18) | 281 (33) |
| 45-54 | 117 (24) | 202 (24) |
| 55-64 | 140 (29) | 163 (19) |
| 65-74 | 114 (24) | 132 (15) |
| 75+ | 24 (5) | 77 (9) |
| Patients with amputation(s) ^a *** | 40 (8) | 13 (2) |
| % anuric** | 145 (35) | 313 (44) |
| Body surface area (BSA)** | | |
| Mean (\pm SD) | 1.88 (\pm 0.26) | 1.84 (\pm 0.24) |
| Median | 1.90 | 1.84 |
| Duration of Dialysis (years)*** | | |
| Mean (\pm SD) | 1.7 (\pm 1.8) | 3.4 (\pm 4.0) |
| Median | 1.2 | 2.0 |
| < 0.5 | 144 (30) | 153 (18) |
| 0.5-0.9 | 73 (15) | 92 (11) |
| 1.0-1.9 | 104 (22) | 174 (20) |
| 2.0+ | 155 (33) | 432 (51) |

^a Amputation (s) defined as a below-knee, below-elbow, or more proximal amputation.

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

Subtotals may not add up to 480 (DM as cause of ESRD) or 855 (other causes combined) due to missing data.

Significant difference between groups: ** $p < 0.01$; *** $p < 0.001$

Anemia Management

There were no significant differences in mean hemoglobin or the percent of patients meeting most thresholds for DM+ patients compared to patients with other causes combined.

There were no significant differences in Epoetin prescription practices or mean prescribed Epoetin doses by either the IV or the subcutaneous (SC) route between groups.

There were no significant differences in either transferrin saturation or serum ferritin concentration between groups. 71% of DM+ patients were prescribed iron by either the intravenous (IV) or the oral route at least once during the three-month study period compared to 65% of patients with other causes combined ($p < 0.05$).

Serum Albumin

The mean (\pm SD) serum albumin was significantly lower for DM+ patients with values determined by the BCG laboratory method ($n=1139$) compared to patients with other causes combined (3.40 gm/dL vs. 3.58 gm/dL, $p < 0.001$) (Table 2). Similar results were obtained for patients whose serum albumin was determined by the BCP method ($n=191$) (not significant [NS]). A significantly smaller percentage of DM+ patients compared to patients with other causes combined had a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) (9% vs. 17%, $p < 0.001$).

Section II: Comparisons Within the DM+ Group

By Gender (Table 3)

DM+ males had significantly lower mean total weekly Kt/V urea values compared to DM+ females (2.23 vs. 2.43, $p < 0.01$), yet had significantly higher mean total creatinine clearance values (81.1 L/wk/1.73m² vs. 71.8 L/wk/1.73 m², $p < 0.01$). 63% of DM+ males compared to 46% of DM+ females had a mean weekly creatinine clearance ≥ 60 L/wk/1.73m² ($p < 0.001$).

DM+ males had significantly higher mean hemoglobin values compared to DM+ females (12.0 gm/dL vs. 11.5 gm/dL, $p < 0.001$), despite being prescribed on average significantly lower Epoetin doses (43.9 units/kg SC vs. 58.1 units/kg SC, $p < 0.001$).

Approximately 80% of DM+ females and DM+ males achieved a mean transferrin saturation $\geq 20\%$. There was no significant difference in the percent of DM+ females or DM+ males achieving a mean serum ferritin concentration ≥ 100 ng/mL (approximately 80% of patients).

No difference in iron prescription patterns was noted between groups, with approximately 70% of patients prescribed iron at least once during the study period. Within this subgroup, approximately 22% were prescribed iron by the IV route.

DM+ males had significantly higher mean serum albumin values compared to DM+ females by the BCG laboratory method (3.47 gm/dL vs. 3.33 gm/dL, $p < 0.01$). A significantly larger percentage of DM+ males achieved a mean serum albumin $\geq 4.0/3.7$ gm/dL compared to DM+ females (12% vs. 7%, $p < 0.05$).

By Race (Table 4)

DM+ black patients had significantly lower mean total weekly Kt/V urea values compared to DM+ white patients (2.22 vs.

Table 2: Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD compared to patients with other causes of ESRD combined, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | DM as cause of ESRD (n=480) | Other causes of ESRD combined (n=855) | Clinical Measure ^a | DM as cause of ESRD (n=480) | Other causes of ESRD combined (n=855) |
|---------------------------------------------------------------|-----------------------------|---------------------------------------|-----------------------------------------------------|-----------------------------|---------------------------------------|
| <i>Adequacy of Dialysis</i> | | | <i>Epoetin dose (units/kg)</i> | | |
| Weekly Kt/V urea | | | IV | | |
| Total clearance: | | | Mean (± SD) | 75.1 (± 37.8) | 61.3 (± 29.8) |
| Mean (± SD) | 2.33 (± 0.57) | 2.30 (± 0.55) | Median | 77.5 | 55.9 |
| Median | 2.25 | 2.23 | SC | | |
| Renal clearance: | | | Mean (± SD) | 51.1 (± 41.2) | 51.7 (± 41.8) |
| Mean (± SD) | 0.76 (± 0.63) | 0.70 (± 0.62) | Median | 37.6 | 39.9 |
| Median | 0.56 | 0.55 | Transferrin Saturation (%) | | |
| Peritoneal clearance: | | | Mean (± SD) | 28.0 (± 9.7) | 29.0 (± 10.8) |
| Mean (± SD) | 1.87 (± 0.48) | 1.92 (± 0.52) | Median | 26.0 | 27.5 |
| Median | 1.83 | 1.93 | Mean transferrin saturation ≥ 20% | 81% | 82% |
| Mean weekly Kt/V ≥ 2.0 | 58% | 58% | Serum ferritin concentration (ng/mL) | | |
| Weekly creatinine clearance (L/wk/1.73m ²) | | | Mean (± SD) | 375 (± 352) | 404 (± 404) |
| Total clearance: | | | Median | 274 | 266 |
| Mean (± SD) | 76.5 (±28.3)** | 71.6% (± 24.7) | Mean serum ferritin ≥ 100 ng/mL | 81% | 82% |
| Median | 70.3 | 65.7 | Patients with relative iron deficiency ^c | 6% | 6% |
| Renal clearance: | | | Patients prescribed iron | 71%* | 65% |
| Mean (± SD) | 45.0 (± 36.6)* | 38.2 (± 36.2) | Within this group: | | |
| Median | 34.2 | 28.6 | prescribed IV | 23% | 23% |
| Peritoneal clearance: | | | prescribed PO | 85% | 86% |
| Mean (± SD) | 51.03 (± 16.1) | 52.3 (± 15.9) | <i>Serum Albumin</i> | | |
| Median | 49.6 | 51.1 | BCG ^d | | |
| Mean weekly creatinine clearance ≥ 60 L/wk/1.73m ² | 54% | 50% | Mean (± SD) | 3.40 (± 0.45)*** | 3.58 (± 0.45) |
| % anuric | 35%** | 44% | Median | 3.43 | 3.60 |
| <i>Anemia Management</i> | | | BCP ^e | | |
| Hemoglobin (gm/dL) | | | Mean (± SD) | 3.15 (± 0.48) | 3.27 (± 0.55) |
| Mean (± SD) | 11.7 (± 1.3) | 11.7 (± 1.4) | Median | 3.18 | 3.27 |
| Median | 11.6 | 11.7 | Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) | 9%*** | 17% |
| Mean Hgb ≥ 11 gm/dL | 74% | 73% | Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) | 47%*** | 62% |
| Mean Hgb 11.0-12.0 gm/dL ^b | 39% | 37% | | | |
| Mean Hgb 11.0-12.9 gm/dL | 60% | 59% | | | |
| Mean Hgb < 10 gm/dL | 7% | 10% | | | |
| Mean Hgb < 9 gm/dL | 1%* | 3% | | | |
| Patients prescribed Epoetin | 89% | 87% | | | |
| Within this group: | | | | | |
| prescribed IV | 5% | 5% | | | |
| prescribed SC | 97% | 98% | | | |

^a Continuous variables are displayed as the mean (± SD) and median values; categorical variables displayed as percent of available values.

^b Among patients prescribed Epoetin

^c Relative iron deficiency is defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

^d BCG = bromcresol green laboratory method

^e BCP = bromcresol purple laboratory method

significant differences between groups noted by: * p < 0.05; ** p < 0.01; *** p < 0.001

2.38, $p < 0.05$) and significantly lower mean total weekly creatinine clearance values (70.6 L/wk/1.73m² vs. 80.0 L/wk/1.73m², $p < 0.01$).

DM+ black patients had significantly lower mean hemoglobin values compared to DM+ white patients (11.5 gm/dL vs. 11.9 gm/dL, $p < 0.05$). 68% of blacks compared to 78% of whites had a mean hemoglobin ≥ 11 gm/dL ($p < 0.05$). There were no significant differences noted for Epoetin prescription practices or Epoetin doses by race.

There were no significant differences noted for mean transferrin saturation or percent of patients with a mean transferrin saturation $\geq 20\%$ by race. DM+ black patients had significantly higher mean serum ferritin concentrations compared to DM+ white patients (432 ng/mL vs. 342 ng/mL, $p < 0.05$). No significant differences were noted for iron prescription patterns by race.

There were no significant differences noted in mean serum albumin by either the BCG or BCP laboratory methods, nor in the percent of patients achieving certain thresholds of mean serum albumin, by race.

By mean BMI (Table 5)

For this analysis, patients with mean BMI ≥ 30 (high BMI) were compared to DM+ patients with lower mean BMI. No significant differences were noted for either total, renal or peritoneal weekly Kt/V or weekly creatinine clearance values by BMI group. Only 51% of patients with high BMI had a mean Kt/V ≥ 2.0 compared to 62% of patients with lower mean BMI ($p < 0.05$).

DM+ patients with high BMI had a significantly lower mean hemoglobin compared to DM+ patients with lower BMI (11.3 gm/dL vs. 11.9 gm/dL, $p < 0.001$). 63% of DM+ patients with high BMI had a mean hemoglobin ≥ 11 gm/dL compared to 79% of DM+ patients with lower BMI ($p < 0.001$).

93% of DM+ patients with high BMI were prescribed Epoetin compared to 88% of DM+ patients with lower BMI. There were no significant differences in mean Epoetin doses by either the IV or the SC route by BMI group.

There were no significant differences in transferrin saturation or serum ferritin concentration between groups. 76% of DM+ patients with high BMI were prescribed iron by some route during the six-month study period compared to 69% of DM+ patients with lower BMI.

There were no significant differences in mean serum albumin values by either the BCG or the BCP laboratory method, nor any significant difference in the percent of patients meeting certain thresholds of mean serum albumin by BMI group.

KEY OBSERVATIONS

- The amputation rate of 8% among peritoneal dialysis DM+ patients is four-fold that of patients with other causes of ESRD.

This suggests that programs to prevent amputations might benefit ESRD patients with diabetes. The high amputation rate may suggest the need for more vigilance of foot care as well as other forms of macrovascular disease (e.g. carotid, coronary) and lipid management in this population.

- DM+ peritoneal dialysis patients are less likely to be anuric. Recent observational studies have suggested that lower residual renal function may contribute disproportionately to risk of death associated with delivered dialysis dose among peritoneal dialysis patients. The role of residual renal function as a risk factor for differential survival among peritoneal dialysis and hemodialysis patients deserves further study.

- Adequacy of dialysis and control of anemia are comparable among DM+ peritoneal dialysis patients and patients with other causes of ESRD.

- Although these data are cross-sectional and no causal associations can be determined, the significantly shorter time the DM+ peritoneal dialysis patients have been on dialysis (mean 1.7 yrs) likely represents a higher mortality rate for these patients compared to peritoneal dialysis patients with other causes of ESRD (mean 3.4 yrs). This finding was noted for the adult hemodialysis patient sample as well. This difference in duration of dialysis therapy may also explain the difference in total clearances between groups.

NEXT STEPS

- There are multiple differences between the DM+ peritoneal dialysis patients and those with other causes of ESRD that suggest DM+ patients may have a higher severity of disease. These include: a) the higher percent of patients with amputation(s); and b) lower serum albumin levels. These findings may signal the need for a different approach to incipient dialysis in patients with diabetes.

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Table 3: Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD, by gender, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | ALL (n=480) | Males (n=236) | Females (n=244) |
|------------------------------------------------------------------|----------------|------------------|--------------------|
| <i>Adequacy of Dialysis</i> | | | |
| Weekly Kt/V urea | | | |
| Total clearance: | | | |
| Mean (± SD) | 2.33 (± 0.57) | 2.23 (± 0.51)** | 2.43 (± 0.62) |
| Median | 2.25 | 2.16 | 2.37 |
| Renal clearance: | | | |
| Mean (± SD) | 0.76 (± 0.63) | 0.73 (± 0.52) | 0.81 (± 0.74) |
| Median | 0.56 | 0.55 | 0.58 |
| Peritoneal clearance: | | | |
| Mean (± SD) | 1.87 (± 0.48) | 1.72 (± 0.42)*** | 2.01 (± 0.49) |
| Median | 1.83 | 1.68 | 1.97 |
| Mean weekly Kt/V ≥ 2.0 | 58% | 54% | 63% |
| Weekly creatinine clearance (L/wk/1.73m ²) | | | |
| Total clearance: | | | |
| Mean (± SD) | 76.5 (±28.3) | 81.1% (± 28.2)** | 71.8 (± 27.7) |
| Median | 70.3 | 73.6 | 64.7 |
| Renal clearance: | | | |
| Mean (± SD) | 45.0 (± 36.6) | 46.1 (± 33.1) | 43.6 (± 40.5) |
| Median | 34.2 | 39.2 | 31.2 |
| Peritoneal clearance: | | | |
| Mean (± SD) | 51.03 (± 16.1) | 51.5 (± 16.6) | 50.5 (± 15.6) |
| Median | 49.6 | 49.6 | 49.6 |
| Mean weekly creatinine clearance ≥ 60 L/wk/1.73m ² | 54% | 63%*** | 46% |
| % anuric | 35% | 28%** | 43% |
| <i>Anemia Management</i> | | | |
| Hemoglobin (gm/dL) | | | |
| Mean (± SD) | 11.7 (± 1.3) | 12.0 (± 1.4)*** | 11.5 (± 1.2) |
| Median | 11.6 | 11.9 | 11.5 |
| Mean Hgb ≥ 11 gm/dL | 74% | 80%** | 68% |
| Mean Hgb 11.0-12.0 gm/dL ^b | 39% | 36% | 42% |
| Mean Hgb 11.0-12.9 gm/dL | 60% | 60% | 59% |
| Mean Hgb < 10 gm/dL | 7% | 5% | 9% |
| Mean Hgb < 9 gm/dL | 1% | 0.8 % | 2% |
| Patients prescribed Epoetin | 89% | 86% | 92% |
| Within this group: | | | |
| prescribed IV | 5% | 4% | 6% |
| prescribed SC | 97% | 99% | 96% |

Table 3(continued): Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD, by gender, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | ALL (n=480) | Males (n=236) | Females (n=244) |
|-----------------------------------------------------|----------------|------------------|--------------------|
| Epoetin dose (units/kg) | | | |
| IV | | | |
| Mean (± SD) | 75.1 (± 37.8) | 80.9 (± 27.4) | 71.7 (± 43.2) |
| Median | 77.5 | 77.5 | 73.3 |
| SC | | | |
| Mean (± SD) | 51.1 (± 41.2) | 43.9 (± 33.3)*** | 58.1 (± 46.7) |
| Median | 37.6 | 33.9 | 44.2 |
| Transferrin Saturation (%) | | | |
| Mean (± SD) | 28.0 (± 9.7) | 28.4 (± 9.6) | 27.7 (± 9.9) |
| Median | 26.0 | 27.2 | 25.7 |
| Mean transferrin saturation ≥ 20% | 81% | 80% | 81% |
| Serum ferritin concentration (ng/mL) | | | |
| Mean (± SD) | 375 (± 352) | 333 (± 291)* | 415 (± 398) |
| Median | 274 | 244 | 296 |
| Mean serum ferritin ≥ 100 ng/mL | 81% | 82% | 80% |
| Patients with relative iron deficiency ^c | 6% | 6% | 6% |
| Patients prescribed iron | 71% | 72% | 71% |
| Within this group: | | | |
| prescribed IV | 23% | 24% | 22% |
| prescribed PO | 85% | 84% | 87% |
| Serum Albumin | | | |
| BCG^d | | | |
| Mean (± SD) | 3.40 (± 0.45) | 3.47 (± 0.44)** | 3.33 (± 0.45) |
| Median | 3.43 | 3.53 | 3.37 |
| BCP^e | | | |
| Mean (± SD) | 3.15 (± 0.48) | 3.17 (± 0.55) | 3.14 (± 0.42) |
| Median | 3.18 | 3.15 | 3.27 |
| Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) | 9% | 12%* | 7% |
| Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) | 47% | 51% | 43% |

^a Continuous variables are displayed as the mean (± SD) and median values; categorical variables displayed as percent of available values.

^b Among patients prescribed Epoetin

^c Relative iron deficiency is defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

^d BCG = bromcresol green laboratory method

^e BCP = bromcresol purple laboratory method

significant differences between groups noted by: * p < 0.05; ** p < 0.01; *** p < 0.001

Table 4: Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD, by race, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | ALL (n=480) | Blacks (n=125) | Whites (n=286) |
|------------------------------------------------------------------|----------------|-------------------|-------------------|
| <i>Adequacy of Dialysis</i> | | | |
| Weekly Kt/V urea | | | |
| Total clearance: | | | |
| Mean (± SD) | 2.33 (± 0.57) | 2.22 (± 0.54)* | 2.38 (± 0.59) |
| Median | 2.25 | 2.15 | 2.31 |
| Renal clearance: | | | |
| Mean (± SD) | 0.76 (± 0.63) | 0.78 (± 0.86) | 0.76 (± 0.53) |
| Median | 0.56 | 0.48 | 0.62 |
| Peritoneal clearance: | | | |
| Mean (± SD) | 1.87 (± 0.48) | 1.87 (± 0.47) | 1.84 (± 0.50) |
| Median | 1.83 | 1.88 | 1.81 |
| Mean weekly Kt/V ≥ 2.0 | 58% | 54% | 58% |
| Weekly creatinine clearance (L/wk/1.73m ²) | | | |
| Total clearance: | | | |
| Mean (± SD) | 76.5 (±28.3) | 70.6% (± 26.0)** | 80.0 (± 29.2) |
| Median | 70.3 | 66.6 | 73.2 |
| Renal clearance: | | | |
| Mean (± SD) | 45.0 (± 36.6) | 44.6 (± 46.4) | 46.3 (± 33.1) |
| Median | 34.2 | 30.5 | 40.5 |
| Peritoneal clearance: | | | |
| Mean (± SD) | 51.03 (± 16.1) | 51.9 (± 17.6) | 50.4 (± 16.6) |
| Median | 49.6 | 49.5 | 49.6 |
| Mean weekly creatinine clearance ≥ 60 L/wk/1.73m ² | 54% | 52% | 57% |
| % anuric | 35% | 43%* | 30% |
| <i>Anemia Management</i> | | | |
| Hemoglobin (gm/dL) | | | |
| Mean (± SD) | 11.7 (± 1.3) | 11.5 (± 1.3)* | 11.9 (± 1.2) |
| Median | 11.6 | 11.5 | 11.8 |
| Mean Hgb ≥ 11 gm/dL | 74% | 68%* | 78% |
| Mean Hgb 11.0-12.0 gm/dL ^b | 39% | 43% | 38% |
| Mean Hgb 11.0-12.9 gm/dL | 60% | 56% | 61% |
| Mean Hgb < 10 gm/dL | 7% | 10% | 5% |
| Mean Hgb < 9 gm/dL | 1% | 2% | 0.7% |
| Patients prescribed Epoetin | 89% | 92% | 88% |
| Within this group: | | | |
| prescribed IV | 5% | ^^ | 5% |
| prescribed SC | 97% | 98% | 97% |

Table 4 (continued): Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD, by race, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | ALL (n=480) | Blacks (n=125) | Whites (n=286) |
|-----------------------------------------------------|----------------|-------------------|-------------------|
| Epoetin dose (units/kg) | | | |
| IV | | | |
| Mean (± SD) | 75.1 (± 37.8) | ^^ | 69.4 (± 46.5) |
| Median | 77.5 | ^^ | 51.2 |
| SC | | | |
| Mean (± SD) | 51.1 (± 41.2) | 50.0 (± 33.6) | 51.2 (± 46.8) |
| Median | 37.6 | 38.6 | 34.6 |
| Transferrin Saturation (%) | | | |
| Mean (± SD) | 28.0 (± 9.7) | 27.6 (± 9.1) | 27.9 (± 9.9) |
| Median | 26.0 | 26.0 | 26.0 |
| Mean transferrin saturation ≥ 20% | 81% | 78% | 81% |
| Serum ferritin concentration (ng/mL) | | | |
| Mean (± SD) | 375 (± 352) | 432 (± 385)* | 342 (± 336) |
| Median | 274 | 348 | 244 |
| Mean serum ferritin ≥ 100 ng/mL | 81% | 85% | 79% |
| Patients with relative iron deficiency ^c | 6% | 4% | 6% |
| Patients prescribed iron | 71% | 74% | 70% |
| Within this group: | | | |
| prescribed IV | 23% | 22% | 22% |
| prescribed PO | 85% | 86% | 85% |
| Serum Albumin | | | |
| BCG^d | | | |
| Mean (± SD) | 3.40 (± 0.45) | 3.40 (± 0.50) | 3.40 (± 0.42) |
| Median | 3.43 | 3.43 | 3.43 |
| BCP^e | | | |
| Mean (± SD) | 3.15 (± 0.48) | 3.00 (± 0.48) | 3.20 (± 0.47) |
| Median | 3.18 | 3.03 | 3.25 |
| Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) | 9% | 11% | 9% |
| Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) | 47% | 47% | 47% |

^a Continuous variables are displayed as the mean (± SD) and median values; categorical variables displayed as percent of available values.

^b Among patients prescribed Epoetin

^c Relative iron deficiency is defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

^d BCG = bromcresol green laboratory method

^e BCP = bromcresol purple laboratory method

^^ n ≤ 10, data not displayed

significant differences between groups noted by: * p < 0.05; ** p < 0.01; *** p < 0.001

Table 5: Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD, by mean BMI group, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | ALL (n=480) | BMI ≥ 30 (n=166) | BMI < 30 (n=295) |
|------------------------------------------------------------------|----------------|---------------------|---------------------|
| <i>Adequacy of Dialysis</i> | | | |
| Weekly Kt/V urea | | | |
| Total clearance: | | | |
| Mean (± SD) | 2.33 (± 0.57) | 2.26 (± 0.58) | 2.35 (± 0.56) |
| Median | 2.25 | 2.14 | 2.29 |
| Renal clearance: | | | |
| Mean (± SD) | 0.76 (± 0.63) | 0.76 (± 0.62) | 0.74 (± 0.61) |
| Median | 0.56 | 0.57 | 0.54 |
| Peritoneal clearance: | | | |
| Mean (± SD) | 1.87 (± 0.48) | 1.81 (± 0.50) | 1.88 (± 0.45) |
| Median | 1.83 | 1.80 | 1.84 |
| Mean weekly Kt/V ≥ 2.0 | 58% | 51%* | 62% |
| Weekly creatinine clearance (L/wk/1.73m ²) | | | |
| Total clearance: | | | |
| Mean (± SD) | 76.5 (±28.3) | 75.5% (± 28.3) | 76.4 (± 28.0) |
| Median | 70.3 | 70.1 | 70.1 |
| Renal clearance: | | | |
| Mean (± SD) | 45.0 (± 36.6) | 47.8 (± 37.9) | 42.0 (± 34.7) |
| Median | 34.2 | 39.2 | 30.4 |
| Peritoneal clearance: | | | |
| Mean (± SD) | 51.03 (± 16.1) | 49.9 (± 15.9) | 50.7 (± 14.9) |
| Median | 49.6 | 48.2 | 49.6 |
| Mean weekly creatinine clearance ≥ 60 L/wk/1.73m ² | 54% | 49% | 57% |
| % anuric | 35% | 35% | 34% |
| <i>Anemia Management</i> | | | |
| Hemoglobin (gm/dL) | | | |
| Mean (± SD) | 11.7 (± 1.3) | 11.3 (± 1.1)*** | 11.9 (± 1.3) |
| Median | 11.6 | 11.4 | 11.8 |
| Mean Hgb ≥ 11 gm/dL | 74% | 63%*** | 79% |
| Mean Hgb 11.0-12.0 gm/dL ^b | 39% | 41% | 38% |
| Mean Hgb 11.0-12.9 gm/dL | 60% | 56% | 61% |
| Mean Hgb < 10 gm/dL | 7% | 9% | 6% |
| Mean Hgb < 9 gm/dL | 1% | 2% | 0.7% |
| Patients prescribed Epoetin | 89% | 93% | 88% |
| Within this group: | | | |
| prescribed IV | 5% | ^^ | 5% |
| prescribed SC | 97% | 96% | 98% |

Table 5 (continued): Selected clinical measures of interest for adult PD patients with DM as the cause of ESRD, by mean BMI group, Oct 2000-Mar 2001. 2001 ESRD CPM Project.

| Clinical Measure ^a | ALL (n=480) | BMI ≥ 30 (n=166) | BMI < 30 (n=295) |
|-----------------------------------------------------|----------------|---------------------|---------------------|
| Epoetin dose (units/kg) | | | |
| IV | | | |
| Mean (± SD) | 75.1 (± 37.8) | 74.3 (± 40.6) | 75.7 (± 37.1) |
| Median | 77.5 | 74.8 | 77.5 |
| SC | | | |
| Mean (± SD) | 51.1 (± 41.2) | 49.9 (± 45.2) | 51.7 (± 39.1) |
| Median | 37.6 | 35.1 | 38.0 |
| Transferrin Saturation (%) | | | |
| Mean (± SD) | 28.0 (± 9.7) | 27.1 (± 10.3) | 28.3 (± 9.2) |
| Median | 26.0 | 25.5 | 27.0 |
| Mean transferrin saturation ≥ 20% | 81% | 77% | 82% |
| Serum ferritin concentration (ng/mL) | | | |
| Mean (± SD) | 375 (± 352) | 390 (± 380) | 351 (± 309) |
| Median | 274 | 276 | 260 |
| Mean serum ferritin ≥ 100 ng/mL | 81% | 83% | 80% |
| Patients with relative iron deficiency ^c | 6% | 6% | 6% |
| Patients prescribed iron | 71% | 76% | 69% |
| Within this group: | | | |
| prescribed IV | 23% | 29% | 20% |
| prescribed PO | 85% | 82% | 86% |
| <i>Serum Albumin</i> | | | |
| BCG ^d | | | |
| Mean (± SD) | 3.40 (± 0.45) | 3.43 (± 0.41) | 3.39 (± 0.47) |
| Median | 3.43 | 3.47 | 3.42 |
| BCP ^e | | | |
| Mean (± SD) | 3.15 (± 0.48) | 3.12 (± 0.47) | 3.15 (± 0.51) |
| Median | 3.18 | 3.27 | 3.13 |
| Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) | 9% | 6% | 10% |
| Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP) | 47% | 48% | 46% |

^a Continuous variables are displayed as the mean (± SD) and median values; categorical variables displayed as percent of available values.

^b Among patients prescribed Epoetin

^c Relative iron deficiency is defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL.

^d BCG = bromcresol green laboratory method

^e BCP = bromcresol purple laboratory method

^{^^} n ≤ 10, data not displayed

significant differences between groups noted by: * p < 0.05; ** p < 0.01; *** p < 0.001