

**A COMPARISON OF INTERMEDIATE OUTCOMES FOR ADULT IN-CENTER HEMODIALYSIS 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**

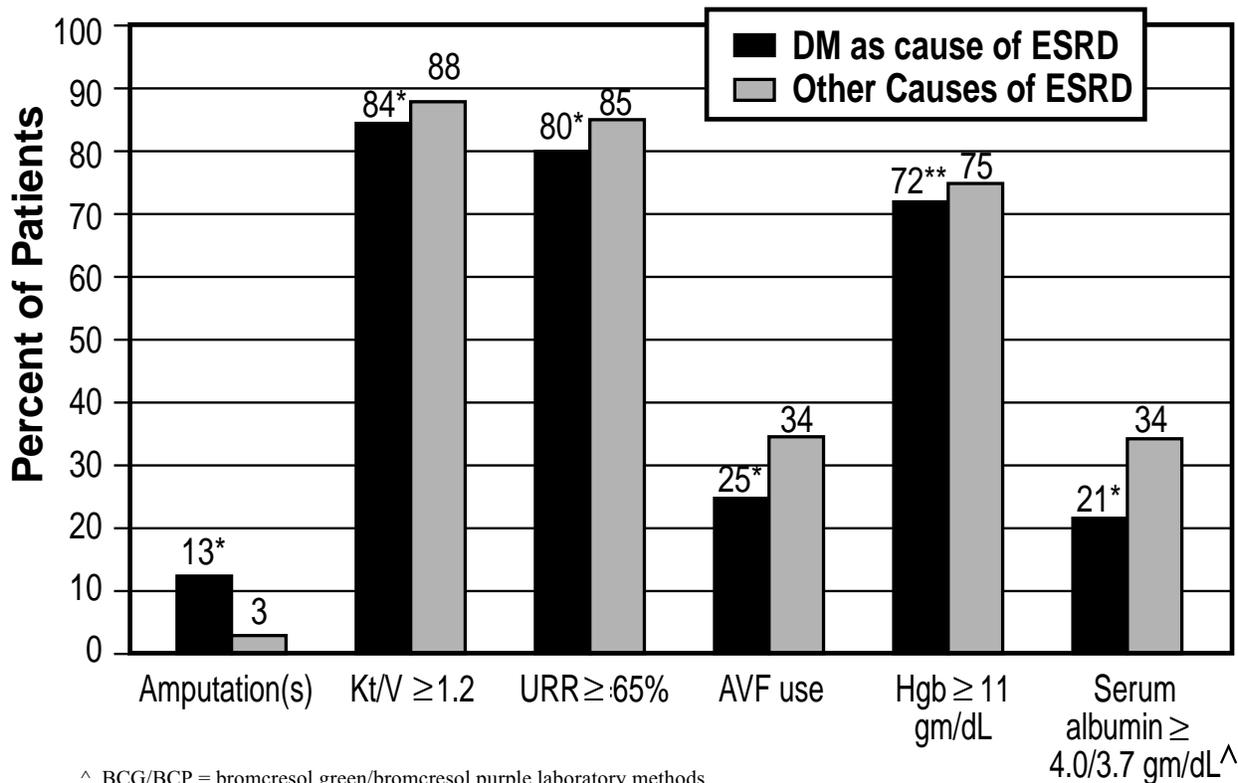
**Supplemental Report #4**

2001 ESRD Clinical Performance Measures Project

The Centers for Medicare & Medicaid Services

April 2002

*Significant Findings for Adult In-Center Hemodialysis Patients in the U.S.,  
by Diabetes Mellitus as the Cause of ESRD vs. Other Causes of ESRD,  
October-December 2000*



<sup>^</sup> 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  $\geq 18$  years) in-center hemodialysis (HD) 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 post-dialysis 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 in-center HD 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, stratified by Network, was drawn. There were 8,853 patients selected for the national sample.

### Data Collection

During May 2001, a three-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 medical record was abstracted for each patient who was receiving in-center HD during the months of October, November, and December 2000. 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, vascular access information, 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, pre- and post-dialysis blood urea nitrogen (BUN) values, dialysis session length to calculate Kt/V values, dialyzer K<sub>Uf</sub> values, type of vascular access, blood pump flow rates, 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

For this report, a patient had to meet the following criteria to remain in the sample for analysis: a data collection form with at least one monthly hemoglobin value, at least one paired pre- and post-dialysis BUN value, and at least one serum albumin value reported over the three month study period. All available reported monthly values were utilized in calculating mean ( $\pm$  SD) and median values. Kt/V values were calculated according to the Daugirdas II formula.<sup>1</sup>

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.6.04a<sup>2</sup> and SPSS for Windows, v. 10.0.<sup>3</sup>

## RESULTS

### The Sample for Analysis

Of the 8853 patients selected for the sample, 8416 (95%) met the inclusion criteria for analysis. 8376/8416 (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. 42% of the patients had DM as the primary cause of ESRD. There was a significantly larger percentage of females, whites, older patients, and heavier patients in the DM+ group. A significantly larger percentage of patients in the DM+ group had an amputation(s) compared to patients with other causes combined (13% vs. 3%,  $p < 0.001$ ).

The distribution of DM+ patients in the sample, by Network, is shown in Figure 1. Areas of the U.S. with the highest proportion of DM+ patients were receiving their dialysis care in the Southwest, California, Texas, New Jersey, the Pacific Northwest, and Florida. The CPM data show that these areas have higher concentrations of Hispanic and American Indian/Alaska Native patients, which may partially account for the higher prevalence of DM+ patients.

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

#### Adequacy of Dialysis

The mean calculated Kt/V value was lower for DM+ patients compared to patients with other causes combined (1.47 vs. 1.51,  $p < 0.001$ ) (Table 2). A smaller percentage of DM+ patients achieved a mean Kt/V  $\geq 1.2$  compared to patients with other causes combined (84% vs. 88%,  $p < 0.001$ ). Similar results were obtained when characterizing adequacy by URR. These lower adequacy results were achieved despite significantly longer dialysis session lengths for DM+ patients.

Table 1: Selected patient characteristics for adult in-center HD patients, Oct-Dec 2000. 2001 ESRD CPM Project.

Characteristic	DM as cause of ESRD n (%)	Other causes of ESRD combined n (%)
TOTAL	3496 (100)	4880 (100)
Gender***		
Male	1652 (47)	2709 (56)
Female	1842 (53)	2170 (45)
Race**		
Black	1192 (34)	1903 (39)
White	1831 (52)	2563 (53)
Ethnicity***		
Hispanic	648 (19)	433 (9)
Non-Hispanic	2702 (77)	4189 (86)
Age (years)***		
Mean (±SD)	62.8 (± 12.4)	60.3 (± 16.9)
Median	64.2	61.5
18-44	317 (9)	1009 (21)
45-54	565 (16)	895 (18)
55-64	954 (27)	814 (17)
65-74	1087 (31)	981 (20)
75+	573 (16)	1181 (24)
Patients with amputation(s) <sup>a</sup> ***	439 (13)	123 (3)
Post-dialysis body mass index (BMI)***		
Mean (± SD)	27.8 (± 6.8)	25.7 (± 6.5)
Median	26.7	24.5
Duration of Dialysis (years)***		
Mean (±SD)	2.6 (± 2.4)	4.1 (± 4.5)
Median	1.9	2.6
< 0.5	502 (14)	489 (10)
0.5-0.9	534 (15)	617 (13)
1.0-1.9	803 (23)	915 (19)
2.0+	1632 (47)	2805 (58)

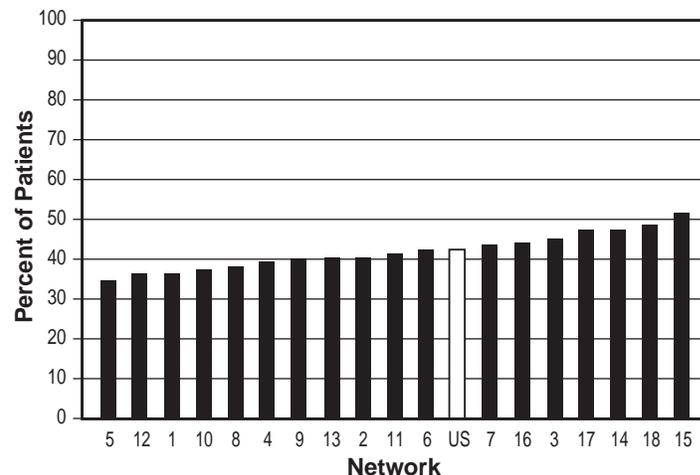
<sup>a</sup> Amputation(s) defined as a below-knee, below-elbow, or more proximal amputation.

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

Subtotals may not add up to 3496 (DM as cause of ESRD) or 4880 (other causes combined) due to missing data.

Significant difference between groups: \*\* p < 0.01, \*\*\* p < 0.001

Figure 1: Percent of patients with diabetes mellitus as the primary cause of ESRD, by Network, October-December 2000. 2001 ESRD CPM Project.



### Vascular Access

25% of prevalent DM+ patients were dialyzed with an AV fistula (AVF) on their last hemodialysis session during the study period compared to 34% of patients with other causes combined (p < 0.001); results were similar for incident patients (24% vs. 30%, p < 0.01) (Table 2). A higher percentage of DM+ patients compared to patients with other causes combined were dialyzed with an AV graft on their last hemodialysis session during the study period (50% vs. 43%, p < 0.001). Approximately 25% of patients in both groups were dialyzed with a catheter (not significant [NS]).

### Anemia Management

The mean (± SD) hemoglobin for DM+ patients was slightly, but significantly, lower than for patients with other causes combined (11.6 gm/dL vs. 11.7 gm/dL, p < 0.001) (Table 2).

38% of patients in both groups who were prescribed Epoetin had a mean hemoglobin within the National Kidney Foundation-Kidney/Disease Outcomes Quality Initiative (NKF-K/DOQI) recommended target range<sup>4</sup> of 11.0-12.0 gm/dL.

96% of DM+ patients were prescribed Epoetin at least once during the three-month study period. Within this subgroup, 90% were prescribed Epoetin by the intravenous (IV) route and 10% by the subcutaneous (SC) route (groups not mutually exclusive). The mean (± SD) Epoetin dose by the IV route was significantly lower for DM+ patients compared to patients with other causes combined (78.2 units/kg vs. 84.7 units/kg, p < 0.001).

The mean (± SD) transferrin saturation value was significantly lower for DM+ patients compared to patients with other causes combined (27.6% vs. 29.0%, p < 0.001). 75% of DM+ patients had a mean transferrin saturation value ≥ 20% compared to 78% of patients with other causes combined (p < 0.01).

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

Clinical Measure <sup>a</sup>	DM as cause of ESRD (n=3496)	Other causes of ESRD combined (n=4880)	Clinical Measure <sup>a</sup>	DM as cause of ESRD (n=3496)	Other causes of ESRD combined (n=4880)
<i>Adequacy of Dialysis</i>			<i>Epoetin dose (units/kg)</i>		
Calculated Kt/V			IV		
Mean (± SD)	1.47 (± 0.29)***	1.51 (± 0.29)	Mean (± SD)	78.2 (± 68.5)***	84.7 (± 72.4)
Median	1.47	1.50	Median	60.5	64.4
Mean Kt/V ≥ 1.2	84%***	88%	SC		
Calculated URR			Mean (± SD)	66.7 (± 52.3)	67.0 (± 52.6)
Mean (± SD)	70.0% (± 7.2%)***	71.1% (± 7.1)	Median	52.8	51.8
Median	70.9%	71.8%	Transferrin Saturation (%)		
Mean URR ≥ 65%	80%***	85%	Mean (± SD)	27.6 (± 12.5)***	29.0 (± 13.0)
Dialysis session length (minutes)			Median	25.3	27.0
Mean (± SD)	217.7 (± 29.3)***	213.9 (± 30.6)	Mean transferrin saturation ≥ 20%	75%**	78%
Median	215.0	210.0	Serum ferritin concentration (ng/mL)		
Dialyzed with a hi-flux dialyzer (KUF ≥ 20 mL/mmHg/hr)	72%	71%	Mean (± SD)	515 (± 382)	532 (± 398)
Blood pump flow rate (mL/minute)			Median	448	459
Mean (± SD)	390.9 (± 70.0)*	394.2 (± 68.6)	Mean serum ferritin ≥ 100 ng/mL	89%	89%
Median	400	400	Patients with relative iron deficiency <sup>c</sup>	5%	4%
<i>Vascular Access<sup>b</sup></i>			Patients prescribed iron	71%*	68%
Type of access			Within this group:		
AV Fistula (all patients)	25%***	34%	prescribed IV	92%	92%
AV Fistula (incident patients <sup>c</sup> )	24%**	30%	prescribed PO	15%	15%
AV graft	50%***	43%	<i>Serum Albumin</i>		
Catheter	26%	24%	BCG <sup>f</sup>		
Catheter in use ≥ 90 days	17%	17%	Mean (± SD)	3.69 (± 0.38)***	3.79 (± 0.38)
<i>Anemia Management</i>			Median	3.73	3.83
Hemoglobin (gm/dL)			BGP <sup>g</sup>		
Mean (± SD)	11.6 (± 1.2)***	11.7 (± 1.2)	Mean (± SD)	3.43 (± 0.45)***	3.58 (± 0.44)
Median	11.6	11.7	Median	3.47	3.63
Mean Hgb ≥ 11 gm/dL	72%**	75%	Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)	21%***	34%
Mean Hgb 11.0-12.0 gm/dL <sup>d</sup>	38%	38%	Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP)	76%***	83%
Mean Hgb 11.0-12.9 gm/dL	62%	63%			
Mean Hgb < 10 gm/dL	9%*	8%			
Mean Hgb < 9 gm/dL	2%	2%			
Patients prescribed Epoetin	96%*	95%			
Within this group:					
prescribed IV	90%	91%			
prescribed SC	10%	11%			

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

<sup>b</sup> Vascular access used on last hemodialysis session during the reporting period.

<sup>c</sup> An incident patient defined as initiating in-center HD on or between January 1, 2000 and August 31, 2000.

<sup>d</sup> Among patients prescribed Epoetin

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

<sup>f</sup> BCG = bromocresol green laboratory method

<sup>g</sup> BCP = bromocresol purple laboratory method

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

There was no significant difference in 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. Within this subset, 92% of patients were prescribed iron by the IV route and 15% by the oral route (groups not mutually exclusive).

### **Serum Albumin**

The mean ( $\pm$  SD) serum albumin was significantly lower for DM+ patients with values determined by the BCG laboratory method ( $n=3034$ ) compared to patients with other causes combined (3.69 gm/dL vs. 3.79 gm/dL,  $p < 0.001$ ) (Table 2). Similar results were obtained for patients whose serum albumin was determined by the BCP method ( $n=444$ ). 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) (21% vs. 34%,  $p < 0.001$ ).

## **Section II: Comparisons Within the DM+ Group**

### **By Gender (Table 3)**

DM+ males had significantly lower mean Kt/V and URR values compared to DM+ females despite having significantly longer dialysis session lengths and significantly higher blood pump flow rates.

DM+ females were significantly less likely to have an AVF as their access compared to DM+ males (17% vs. 34% for prevalent patients, 15% vs. 34% for incident patients,  $p < 0.001$ ). DM+ females were also more likely to have a catheter as their access compared to DM+ males (28% vs. 23%,  $p < 0.001$ ) and to have a catheter in place for 90 days or longer (20% vs. 14%,  $p < 0.001$ ).

DM+ males had significantly higher mean hemoglobin values compared to DM+ females (11.7 gm/dL vs. 11.5 gm/dL,  $p < 0.001$ ), despite being prescribed on average significantly lower Epoetin doses (70.4 units/kg IV vs. 85.0 units/kg IV,  $p < 0.001$ ).

Approximately 75% 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  $\geq 100$  ng/mL (approximately 90% 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 92% were prescribed iron by the IV route.

DM+ males had significantly higher mean serum albumin values compared to DM+ females by both the BCG and BCP laboratory methods. A significantly larger percentage of DM+ males achieved a mean serum albumin  $\geq 4.0/3.7$  gm/dL compared to DM+ females (28% vs. 15%,  $p < 0.001$ ).

### **By Race (Table 4)**

DM+ blacks had significantly lower mean Kt/V values compared to DM+ whites (1.45 vs. 1.47,  $p < 0.05$ ) despite having significantly longer dialysis session lengths and significantly higher blood pump flow rates.

DM+ blacks were significantly less likely to have an AVF as their access compared to DM+ whites (19% vs. 27% for prevalent patients,  $p < 0.001$ ). DM+ blacks were also less likely to have a catheter as their access compared to DM+ whites (23% vs. 28%,  $p < 0.01$ ).

There were no significant differences noted for mean hemoglobin or patients achieving different thresholds for mean hemoglobin by race. DM+ blacks were prescribed significantly higher mean Epoetin doses compared to DM+ whites (82.7 units/kg vs. 75.6 units/kg,  $p < 0.05$ ). DM+ blacks had significantly higher mean transferrin saturation values and serum ferritin concentrations compared to DM+ whites. 78% of DM+ blacks compared to 74% of DM+ whites achieved a mean transferrin saturation  $\geq 20\%$  ( $p < 0.05$ ). 92% of DM+ blacks compared to 88% of DM+ whites achieved a mean serum ferritin concentration  $\geq 100$  ng/mL ( $p < 0.001$ ). No significant differences were noted for iron prescription patterns by race.

By the BCP laboratory method only, DM+ blacks had a significantly higher mean serum albumin value compared to DM+ whites (3.54 gm/dL vs. 3.38 gm/dL,  $p < 0.01$ ). A significantly larger percentage of DM+ blacks achieved a mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP) compared to DM+ whites (79% vs. 74%,  $p < 0.01$ ).

### **By mean post-dialysis BMI (Table 5)**

For this analysis, patients with mean post-dialysis BMI  $\geq 30$  (high BMI) were compared to DM+ patients with lower mean post-dialysis BMI. DM+ patients with high BMI had significantly lower mean Kt/V and URR values compared to DM+ patients with lower BMI despite having significantly longer dialysis session lengths and significantly higher blood pump flow rates.

DM+ patients with high BMI were less likely to be dialyzed with an AVF compared to DM+ patients with lower BMI (21% vs. 27%,  $p < 0.001$ ), and more likely to be dialyzed with an AV graft (54% vs. 48%,  $p < 0.01$ ). No difference in catheter use between groups was noted.

There were no significant differences noted for mean hemoglobin or patients achieving different thresholds for mean hemoglobin by BMI group. DM+ patients with high BMI had significantly lower mean transferrin saturation values compared to DM+ patients with lower BMI (26.7% vs. 28.0%,  $p < 0.01$ ). No significant difference was noted in serum ferritin concentration between groups. No significant differences were noted for iron prescription patterns by BMI group.

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

Clinical Measure <sup>a</sup>	ALL (n=3496)	Males (n=1652)	Females (n=1842)
<i>Adequacy of Dialysis</i>			
Calculated Kt/V			
Mean (± SD)	1.47 (± 0.29)	1.41 (± 0.27)***	1.53 (± 0.29)
Median	1.47	1.42	1.53
Mean Kt/V ≥ 1.2	84%	79%***	89%
Calculated URR			
Mean (± SD)	70.0% (± 7.2%)	68.3% (± 7.1%)***	71.6% (± 7.1%)
Median	70.9%	69.3	72.6
Mean URR ≥ 65%	80%	73%***	86%
Dialysis session length (minutes)			
Mean (± SD)	217.7 (± 29.3)	224.9 (± 29.1)***	211.3 (± 27.9)
Median	215.0	230.0	210.0
Dialyzed with a hi-flux dialyzer (KUF ≥ 20 mL/mmHg/hr)	72%	74%***	69%
Blood pump flow rate (mL/minute)			
Mean (± SD)	390.9 (± 70.0)	399.3 (± 68.8)***	383.3 (± 70.3)
Median	400	400	400
<i>Vascular Access<sup>b</sup></i>			
Type of access			
AV Fistula (all patients)	25%	34%***	17%
AV Fistula (incident patients <sup>c</sup> )	24%	34%***	15%
AV graft	50%	43%***	55%
Catheter	26%	23%***	28%
Catheter in use ≥ 90 days	17%	14%***	20%
<i>Anemia Management</i>			
Hemoglobin (gm/dL)			
Mean (± SD)	11.6 (± 1.2)	11.7 (± 1.3)***	11.5 (± 1.2)
Median	11.6	11.7	11.6
Mean Hgb ≥ 11 gm/dL	72%	74%	71%
Mean Hgb 11.0-12.0 gm/dL <sup>d</sup>	38%	36%	39%
Mean Hgb 11.0-12.9 gm/dL	62%	61%	63%
Mean Hgb < 10 gm/dL	9%	9%	10%
Mean Hgb < 9 gm/dL	2%	2%	2%
Patients prescribed Epoetin	96%	96%*	97%
Within this group:			
prescribed IV	90%	90%	90%
prescribed SC	10%	10%	11%

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

Clinical Measure <sup>a</sup>	ALL (n=3496)	Males (n=1652)	Females (n=1842)
<b>Epoetin dose (units/kg)</b>			
<b>IV</b>			
Mean (± SD)	78.2 (± 68.5)	70.4 (± 65.4)***	85.0 (± 70.5)
Median	60.5	53.5	67.0
<b>SC</b>			
Mean (± SD)	66.7 (± 52.3)	59.8 (± 42.0)*	72.5 (± 59.2)
Median	52.8	48.0	59.6
<b>Transferrin Saturation (%)</b>			
Mean (± SD)	27.6 (± 12.5)	28.1 (± 12.4)*	27.2 (± 12.6)
Median	25.3	26.0	24.7
Mean transferrin saturation ≥ 20%	75%	77%	74%
<b>Serum ferritin concentration (ng/mL)</b>			
Mean (± SD)	515 (± 382)	492 (± 373)**	537 (± 390)
Median	448	424	480
Mean serum ferritin ≥ 100 ng/mL	89%	89%	90%
Patients with relative iron deficiency <sup>e</sup>	5%	5%	5%
Patients prescribed iron	71%	71%	70%
Within this group:			
prescribed IV	92%	93%	92%
prescribed PO	15%	15%	15%
<b>Serum Albumin</b>			
<b>BCG<sup>f</sup></b>			
Mean (± SD)	3.69 (± 0.38)	3.74 (± 0.39)***	3.64 (± 0.37)
Median	3.73	3.80	3.70
<b>BCP<sup>g</sup></b>			
Mean (± SD)	3.43 (± 0.45)	3.49 (± 0.47)**	3.36 (± 0.41)
Median	3.47	3.53	3.40
Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)	21%	28%***	15%
Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP)	76%	79%***	72%

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

<sup>b</sup> Vascular access used on last hemodialysis session during the reporting period.

<sup>c</sup> An incident patient defined as initiating in-center HD on or between January 1, 2000 and August 31, 2000.

<sup>d</sup> Among patients prescribed Epoetin

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

<sup>f</sup> BCG = bromcresol green laboratory method

<sup>g</sup> 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 HD patients with DM as the cause of ESRD, by race, Oct-Dec 2000. 2001 ESRD CPM Project.

Clinical Measure <sup>a</sup>	ALL (n=3496)	Blacks (n=1192)	Whites (n=1831)
<i>Adequacy of Dialysis</i>			
Calculated Kt/V			
Mean (± SD)	1.47 (± 0.29)	1.45 (± 0.28)*	1.47 (± 0.28)
Median	1.47	1.45	1.46
Mean Kt/V ≥ 1.2	84%	82%	84%
Calculated URR			
Mean (± SD)	70.0% (± 7.2%)	69.5% (± 7.2%)	70.0% (± 7.2%)
Median	70.9%	70.6	70.7
Mean URR ≥ 65%	80%	77%	80%
Dialysis session length (minutes)			
Mean (± SD)	217.7 (± 29.3)	222.1 (± 27.8)***	216.2 (± 29.6)
Median	215.0	225.0	210.3
Dialyzed with a hi-flux dialyzer (KUF ≥ 20 mL/mmHg/hr)	72%	72%	73%
Blood pump flow rate (mL/minute)			
Mean (± SD)	390.9 (± 70.0)	403.5 (± 73.0)***	384.4 (± 68.0)
Median	400	400	400
<i>Vascular Access<sup>b</sup></i>			
Type of access			
AV Fistula (all patients)	25%	19%***	27%
AV Fistula (incident patients <sup>c</sup> )	24%	20%	25%
AV graft	50%	58%***	45%
Catheter	26%	23%**	28%
Catheter in use ≥ 90 days	17%	16%	18%
<i>Anemia Management</i>			
Hemoglobin (gm/dL)			
Mean (± SD)	11.6 (± 1.2)	11.5 (± 1.2)	11.6 (± 1.2)
Median	11.6	11.6	11.7
Mean Hgb ≥ 11 gm/dL	72%	72%	73%
Mean Hgb 11.0-12.0 gm/dL <sup>d</sup>	38%	38%	37%
Mean Hgb 11.0-12.9 gm/dL	62%	63%	62%
Mean Hgb < 10 gm/dL	9%	10%	9%
Mean Hgb < 9 gm/dL	2%	2%	2%
Patients prescribed Epoetin	96%	96%	96%
Within this group:			
prescribed IV	90%	91%	90%
prescribed SC	10%	9%*	12%

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

Clinical Measure <sup>a</sup>	ALL (n=3496)	Blacks (n=1192)	Whites (n=1831)
<b>Epoetin dose (units/kg)</b>			
<b>IV</b>			
Mean ( $\pm$ SD)	78.2 ( $\pm$ 68.5)	82.7 ( $\pm$ 70.9)*	75.6 ( $\pm$ 66.7)
Median	60.5	63.1	58.9
<b>SC</b>			
Mean ( $\pm$ SD)	66.7 ( $\pm$ 52.3)	67.4 ( $\pm$ 45.5)	65.8 ( $\pm$ 51.2)
Median	52.8	61.9	53.1
<b>Transferrin Saturation (%)</b>			
Mean ( $\pm$ SD)	27.6 ( $\pm$ 12.5)	28.5 ( $\pm$ 13.1)**	26.9 ( $\pm$ 11.8)
Median	25.3	26.0	25.0
Mean transferrin saturation $\geq$ 20%	75%	78%*	74%
<b>Serum ferritin concentration (ng/mL)</b>			
Mean ( $\pm$ SD)	515 ( $\pm$ 382)	560 ( $\pm$ 402)***	480 ( $\pm$ 364)
Median	448	493	419
Mean serum ferritin $\geq$ 100 ng/mL	89%	92%***	88%
Patients with relative iron deficiency <sup>e</sup>	5%	4%*	6%
Patients prescribed iron	71%	72%	72%
Within this group:			
prescribed IV	92%	93%	93%
prescribed PO	15%	15%	14%
<b>Serum Albumin</b>			
<b>BCG<sup>f</sup></b>			
Mean ( $\pm$ SD)	3.69 ( $\pm$ 0.38)	3.70 ( $\pm$ 0.37)	3.68 ( $\pm$ 0.39)
Median	3.73	3.73	3.70
<b>BCP<sup>g</sup></b>			
Mean ( $\pm$ SD)	3.43 ( $\pm$ 0.45)	3.54 ( $\pm$ 0.37)**	3.38 ( $\pm$ 0.48)
Median	3.47	3.57	3.43
Mean serum albumin $\geq$ 4.0/3.7 gm/dL (BCG/BCP)	21%	22%	20%
Mean serum albumin $\geq$ 3.5/3.2 gm/dL (BCG/BCP)	76%	79%**	74%

<sup>a</sup> Continuous variables are displayed as the mean ( $\pm$  SD) and median values; categorical variables displayed as percent of available values.

<sup>b</sup> Vascular access used on last hemodialysis session during the reporting period.

<sup>c</sup> An incident patient defined as initiating in-center HD on or between January 1, 2000 and August 31, 2000.

<sup>d</sup> Among patients prescribed Epoetin

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

<sup>f</sup> BCG = bromcresol green laboratory method

<sup>g</sup> BCP = bromcresol purple laboratory method

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

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

Clinical Measure <sup>a</sup>	ALL (n=3496)	BMI ≥ 30 (n=1047)	BMI < 30 (n=2337)
<i>Adequacy of Dialysis</i>			
Calculated Kt/V			
Mean (± SD)	1.47 (± 0.29)	1.38 (± 0.27)***	1.52 (± 0.29)
Median	1.47	1.39	1.51
Mean Kt/V ≥ 1.2	84%	77%***	88%
Calculated URR			
Mean (± SD)	70.0% (± 7.2%)	68.0% (± 7.7%)***	71.0% (± 6.8%)
Median	70.9%	69.2	71.7
Mean URR ≥ 65%	80%	72%***	83%
Dialysis session length (minutes)			
Mean (± SD)	217.7 (± 29.3)	227.9 (± 30.7)***	213.1 (± 27.5)
Median	215.0	233.0	210.0
Dialyzed with a hi-flux dialyzer (KUF ≥ 20 mL/mmHg/hr)	72%	76%***	70%
Blood pump flow rate (mL/minute)			
Mean (± SD)	390.9 (± 70.0)	399.5 (± 70.9)***	387.8 (± 69.1)
Median	400	400	400
<i>Vascular Access<sup>b</sup></i>			
Type of access			
AV Fistula (all patients)	25%	21%***	27%
AV Fistula (incident patients <sup>c</sup> )	24%	20%	25%
AV graft	50%	54%**	48%
Catheter	26%	25%	25%
Catheter in use ≥ 90 days	17%	17%	17%
<i>Anemia Management</i>			
Hemoglobin (gm/dL)			
Mean (± SD)	11.6 (± 1.2)	11.5 (± 1.2)	11.6 (± 1.2)
Median	11.6	11.6	11.7
Mean Hgb ≥ 11 gm/dL	72%	71%	73%
Mean Hgb 11.0-12.0 gm/dL <sup>d</sup>	38%	38%	37%
Mean Hgb 11.0-12.9 gm/dL	62%	62%	62%
Mean Hgb < 10 gm/dL	9%	10%	9%
Mean Hgb < 9 gm/dL	2%	2%	2%
Patients prescribed Epoetin	96%	96%**	97%
Within this group:			
prescribed IV	90%	91%	90%
prescribed SC	10%	10%	11%

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

Clinical Measure <sup>a</sup>	ALL (n=3496)	BMI ≥ 30 (n=1047)	BMI < 30 (n=2337)
<b>Epoetin dose (units/kg)</b>			
<b>IV</b>			
Mean (± SD)	78.2 (± 68.5)	69.3 (± 56.3)***	82.3 (± 72.8)
Median	60.5	55.8	62.5
<b>SC</b>			
Mean (± SD)	66.7 (± 52.3)	61.8 (± 53.0)	69.1 (± 52.5)
Median	52.8	45.4	59.7
<b>Transferrin Saturation (%)</b>			
Mean (± SD)	27.6 (± 12.5)	26.7 (± 11.2)**	28.0 (± 12.9)
Median	25.3	25.0	25.5
Mean transferrin saturation ≥ 20%	75%	75%	76%
<b>Serum ferritin concentration (ng/mL)</b>			
Mean (± SD)	515 (± 382)	510 (± 385)	519 (± 382)
Median	448	441	451
Mean serum ferritin ≥ 100 ng/mL	89%	90%	90%
Patients with relative iron deficiency <sup>e</sup>	5%	5%	5%
Patients prescribed iron	71%	73%	70%
Within this group:			
prescribed IV	92%	93%	92%
prescribed PO	15%	14%	15%
<b>Serum Albumin</b>			
<b>BCG<sup>f</sup></b>			
Mean (± SD)	3.69 (± 0.38)	3.68 (± 0.36)	3.69 (± 0.40)
Median	3.73	3.70	3.73
<b>BCP<sup>g</sup></b>			
Mean (± SD)	3.43 (± 0.45)	3.47 (± 0.40)	3.41 (± 0.46)
Median	3.47	3.50	3.47
Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)	21%	19%*	22%
Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP)	76%	77%	75%

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

<sup>b</sup> Vascular access used on last hemodialysis session during the reporting period.

<sup>c</sup> An incident patient defined as initiating in-center HD on or between January 1, 2000 and August 31, 2000.

<sup>d</sup> Among patients prescribed Epoetin

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

<sup>f</sup> BCG = bromcresol green laboratory method

<sup>g</sup> BCP = bromcresol purple laboratory method

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

Although there were no significant differences in mean serum albumin by either the BCG or the BCP laboratory method, a significantly smaller percentage of DM+ patients with high BMI achieved a mean serum albumin  $\geq 4.0/3.7$  gm/dL compared to DM+ patients with lower BMI (19% vs. 22%,  $p < 0.05$ ).

## KEY OBSERVATIONS

- The amputation rate of 13% among DM+ hemodialysis patients is four-fold that of non-diabetics. This suggests that programs to prevent amputations might benefit ESRD patients with diabetes. This high amputation rate among DM+ patients 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.
- Both new (incident) and established (prevalent) DM+ hemodialysis patients are less likely to have an AVF in place compared to patients with other causes of ESRD. Incident and prevalent DM+ patients who are black, female, and those who have a BMI  $\geq 30$  are at greatest risk of not having an AVF.
- DM+ ESRD patients are less likely to achieve the K/DOQI recommended dialysis dose compared to patients with other causes of ESRD. DM+ hemodialysis patients who have a BMI  $\geq 30$  and males are most at-risk of inadequate dialysis. Particular attention should be devoted to adequate prescription of dialysis in these patients.
- Although these data are cross-sectional and no causal associations can be determined, the significantly shorter time the DM+ hemodialysis patients have been on dialysis (mean 2.6 yrs) likely represents a higher mortality rate for these patients compared to hemodialysis patients with other causes of ESRD (mean 4.1 yrs). This finding was noted for the adult peritoneal dialysis patient sample as well.

## NEXT STEPS

- There are multiple differences between the DM+ hemodialysis 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); b) the higher percent of patients with AV grafts; and c) lower serum albumin levels. These findings may signal the need for a different approach to incipient dialysis in patients with diabetes.
- Multivariable analyses will be conducted to more completely understand the gender/race differences noted in the analyses performed for this report.

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