

# ANALYSIS OF INTERMEDIATE OUTCOMES FOR ADULT PERITONEAL DIALYSIS PATIENTS WITH DIABETES: RESULTS FROM THE 2002 END-STAGE RENAL DISEASE (ESRD) CLINICAL PERFORMANCE MEASURES (CPM) PROJECT

## Supplemental Report #4

May 2003

2002 ESRD Clinical Performance Measures Project

## Department of Health and Human Services

The Centers for Medicare & Medicaid Services

### INTRODUCTION

The purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of End-Stage Renal Disease (ESRD) services in the assessment of care provided to ESRD patients and to stimulate improvement in that care. Because of our interest in understanding whether there are differences in practice patterns of care and intermediate outcomes for ESRD patients with diabetes compared to ESRD patients without diabetes, information regarding diabetic diagnosis and associated medication use was collected for the first time in 2002 on a sample of peritoneal dialysis (PD) patients in the U.S. aged  $\geq 18$  years.

This report provides information on responses to questions from the 2002 ESRD CPM data collection form regarding diabetic diagnosis and associated medication use and describes associations of selected intermediate outcomes by category of diabetes.

### METHODS

A random sample was drawn of PD patients (aged  $\geq 18$  years), identified by the 18 ESRD Networks as alive and receiving PD on December 31, 2001.

#### Data Collection

During May 2002, a four-page PD data collection form was sent to each facility that had one or more selected PD patients aged  $\geq 18$  years dialyzing at that facility. Staff at the facility abstracted clinical information from the medical record for each selected patient who was receiving PD during the months of October-November 2001, December 2001-January 2002, and February-March 2002. Patient characteristic information collected included gender, age, race, Hispanic ethnicity, years on dialysis, primary cause of ESRD, and the presence of amputation(s).

Clinical information used to assess the quality of care provided to these patients included the following: patient height and weight, data needed to calculate weekly Kt/V urea and weekly creatinine clearance values, hemoglobin values, prescribed Epoetin alfa 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 them (bromocresol green [BCG] or bromocresol purple [BCP]).

Items added to the data collection form to describe the subset of ESRD patients with diabetes included:

*Has the patient ever been diagnosed with any type of diabetes? If yes,*

*Is the patient currently taking medications to control the diabetes? If yes, is the patient using insulin?*

The responses to these questions were self-reported by dialysis facility staff. We did not define diabetes, but allowed each abstractor to determine, by documentation in the patient's medical record or other means, if the patient had ever been diagnosed with diabetes.

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

### Data Analysis

The following diabetes categories were utilized in the analyses: no diabetes compared to a history of diabetes, and separately, within the subset of patients with diabetes: 1) diabetes, no medications; 2) diabetes, on medications, but not insulin; and 3) diabetes, using insulin. For this report, all available information was used to calculate means, medians, and threshold 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,<sup>1</sup> and body surface area (BSA [m<sup>2</sup>]) was calculated using the formula by Dubois and Dubois.<sup>2</sup>

Due to the small numbers of persons in racial categories other than black and white, analyses by race were limited to these two racial groups. Associations of clinical data with patient characteristics were tested by Chi square, hierarchical ANOVA, and two-tailed Student's t-test. A p-value  $< 0.05$  was considered to be significant.

The data analyses were conducted utilizing SAS v. 8.02<sup>3</sup> and SPSS for Windows, v. 10.0.<sup>4</sup>

## RESULTS

1342/1352 (99%) patients in the sample had information regarding diabetic diagnosis reported. Within the group of patients with diabetic status reported, 789 (59%) did not have diabetes, 50 (4%) had diabetes but were not on medications to treat the diabetes, 75 (6%) had diabetes and were on medications, but not insulin, and 428 (32%) had diabetes and were using insulin. Patients with diabetes were less likely to be Black and more likely to be older and have a higher mean body surface area (BSA) (Table 1a). They were also more likely to have dialyzed fewer years than patients with no history of diabetes. Within the subset of patients with diabetes, those currently using insulin were more likely to be younger than patients with diabetes on no medications to treat their diabetes and patients with diabetes on medications but not insulin (Table 1b). Patients with diabetes but not treated with medication tended to have dialyzed more years compared to patients with diabetes being treated with either medications, not insulin or treated with insulin.

Table 1a: Selected patient characteristics by diabetes category

Patient Characteristic	No Diabetes (n=789)	History of Diabetes (n=553)
% Male	50	50
% Female	50	50
Race		
% White**	62	68
% Black**	29	22
Ethnicity		
% Hispanic***	10	15
Age (years)		
Mean (± SD)*	52.4 (± 16.9)	58.9 (± 13.5)
Median	51.0	60.5
Age group (years)*		
% 18-44	36	17
% 45-64	38	46
% 65+	26	37
% with diabetes mellitus as cause of ESRD^^	2	81
Duration of dialysis (years)		
Mean (± SD)*	3.1 (± 3.7)	1.8 (± 2.2)
Median	2.0	1.3
% with amputation(s)^^	+	9
BSA^^^		
Mean (± SD)*	1.85 (± 0.27)	1.92 (± 0.25)
Median	1.84	1.90

Significant difference among DM groups noted by: \*p < 0.001; \*\* p < 0.01; \*\*\* p < 0.05

+ Value suppressed because n < 11

^ Diabetes mellitus as cause of ESRD was derived from information on the CMS 2728 form. "No Diabetes" categorization was derived from information supplied on the 2002 ESRD CPM data collection form.

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

^^^ BSA – body surface area

Table 1b: Selected patient characteristics by diabetes category

Patient Characteristic	Diabetes, no meds (n=50)	Diabetes, meds (not insulin) (n=75)	Diabetes, insulin (n=428)
% Male	46	56	50
% Female	54	44	51
Race			
% White	60	64	69
% Black	30	21	22
Ethnicity			
% Hispanic	+	+	15
Age (years)			
Mean (± SD)*	60.6 (± 14.2)	64.3 (± 12.9)	57.7 (± 13.3)
Median	62.5	65.9	59.3
Age group (years)**			
% 18-44	16	7	19
% 45-64	40	40	47
% 65+	44	53	34
% with diabetes mellitus as cause of ESRD^^	52	63	87
Duration of dialysis (years)			
Mean (± SD)*	2.1 (± 2.3)	1.7 (± 1.9)	1.8 (± 2.3)
Median	1.3	1.4	1.3
% with amputation(s)^^	+	+	10
BSA^^^			
Mean (± SD)	1.85 (± 0.22)	1.91 (± 0.28)	1.93 (± 0.25)
Median	1.82	1.86	1.91

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

Significant difference among DM groups noted by: \*p < 0.001; \*\* p < 0.01

+ Value suppressed because n < 11

^ Diabetes mellitus as cause of ESRD was derived from information on the CMS 2728 form. "Diabetes" categorization was derived from information supplied on the 2002 ESRD CPM data collection form.

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

^^^ BSA – body surface area

## Patients with Diabetes Compared to Patients without Diabetes (Table 2)

### Adequacy of Dialysis

Although there were no significant differences in total weekly Kt/V urea or in the proportion of patients attaining a mean weekly Kt/V urea ≥ 2.0 across diabetic categories, peritoneal clearance of Kt/V urea was lower in patients with diabetes compared to patients without diabetes. The higher values for the total and renal clearances for creatinine clearance are

likely secondary to the shorter duration of dialysis in patients with diabetes compared to patients without diabetes. Approximately one-third of patients with diabetes and patients without diabetes were anuric.

### **Anemia Management**

There were no significant differences in attaining several hemoglobin thresholds by diabetic category.

Mean transferrin saturation values were slightly lower for patients with diabetes compared to patients without diabetes ( $p < 0.05$ ). Similar percentages of patients in both groups had a mean transferrin saturation  $\geq 20\%$ . There were no significant differences between groups in mean serum ferritin concentration values or in having a mean serum ferritin concentration  $\geq 100$  ng/mL or  $> 800$  ng/mL.

There was no significant difference in the prescription of subcutaneous Epoetin alfa between groups.

There were no significant differences in iron prescription practices between groups, with 66% of patients prescribed some form of iron at least once during the study period. Within the subset of patients prescribed iron, approximately 30% of patients in both groups were prescribed iron by the intravenous route.

### **Serum Albumin**

Patients with diabetes were more likely to have lower mean serum albumin values by either the BCG or the BCP laboratory method compared to patients without diabetes, and fewer achieved a mean serum albumin  $\geq 4.0/3.7$  gm/dL or  $\geq 3.5/3.2$  gm/dL (BCG/BCP).

#### **Within the Subset of Patients with Diabetes (Table 3)**

### **Adequacy of Dialysis**

There were no significant differences in dialysis adequacy thresholds across diabetic categories. Approximately one-third of patients in all groups were anuric.

### **Anemia Management**

There were no significant differences in attaining several hemoglobin thresholds by diabetic category.

Subcutaneous weekly Epoetin alfa doses were similar across groups.

There were no significant differences in iron indices across groups. Iron prescription practices were similar across groups, with approximately two-thirds of patients in all diabetic categories prescribed iron at least once during the study period.

### **Serum Albumin**

Patients with diabetes currently using insulin tended to have lower mean serum albumin values by the BCG laboratory method compared to patients in the other diabetic categories ( $p < 0.05$ ), and fewer attained a mean serum albumin  $\geq 3.5/3.2$  gm/dL (BCG/BCP over the study period ( $p < 0.001$ ).

## **KEY OBSERVATIONS**

### ***Patients with Diabetes Compared to Patients without Diabetes***

- Peritoneal dialysis patients with diabetes are more likely to be white, older, have a higher BSA, and a shorter duration of dialysis compared to patients without diabetes.
- Peritoneal dialysis patients with diabetes are more likely to have a lower peritoneal clearance for Kt/V urea compared to patients without diabetes.
- Peritoneal dialysis patients with diabetes are more likely to have a higher total and renal creatinine clearance compared to patients without diabetes. These findings are likely due to the shorter duration of dialysis in patients with diabetes.

### ***Within the Subset of Patients with Diabetes***

- Patients with diabetes treated with insulin are more likely to be younger than patients with diabetes not treated with insulin.
- Patients with diabetes treated with insulin are more likely to have a lower serum albumin level than patients with diabetes not treated with insulin.

## **NEXT STEPS**

Further analysis will be conducted to more completely understand the associations of these intermediate outcomes of care by diabetic category.

## **REFERENCES**

1. Watson PE, Watson ID, Batt RD. Total body water volumes for adult males and females estimated from simple anthropometric measurements. *Am J Clin Nutr* 33:27-39, 1980.
2. Dubois D, Dubois EF. A formula to estimate the approximate surface area if height and weight be known. *Arch Intern Med* 17:863-871, 1916.
3. The SAS System for Windows, v. 8.02. Cary, NC.
4. Norusis MJ. SPSS for Windows Advanced Statistics, Release 10.0. Chicago, IL, 1999.

Table 2: Selected intermediate outcomes by diabetes category

Clinical Measure <sup>a</sup>	No Diabetes (n=789)	History of Diabetes (n=553)	Clinical Measure <sup>a</sup>	No Diabetes (n=789)	History of Diabetes (n=553)
<i>Adequacy of Dialysis</i>			Weekly Epoetin alfa dose (units/kg/week)		
Weekly Kt/V urea			IV		
Total clearance			Mean (± SD)		
Mean (± SD)	2.35 (± 0.59)	2.36 (± 0.63)		174.1 (± 123.4)	131.0 (± 83.7)
Median	2.27	2.26	Median		
				154.8	105.6
Renal clearance:			SC		
Mean (± SD)	0.76 (± 0.67)	0.84 (± 0.69)	Mean (± SD)*		
Median	0.59	0.60		156.3 (± 116.9)	130.2 (± 85.4)
Peritoneal clearance:			Median		
Mean (± SD)**	1.92 (± 0.50)	1.82 (± 0.47)		127.7	111.3
Median	1.89	1.79	Transferrin saturation (%)		
Mean weekly Kt/V ≥ 2.0	496 (74)	318 (70)	Mean (± SD)***		
				29.9 (± 12.1)	28.4 (± 10.5)
			Median		
				27.7	27.0
Weekly creatinine clearance (L/wk/1.73m <sup>2</sup> )			Mean transferrin saturation		
Total clearance:			≥ 20%		
Mean (± SD)**	71.1 (± 25.4)	75.6 (± 30.4)		625 (84)	433 (82)
Median	65.9	68.1	Serum ferritin concentration (ng/mL)		
Renal clearance:			Mean (± SD)		
Mean (± SD)*	39.5 (± 35.0)	50.2 (± 47.3)		399.4 (± 358.2)	396.6 (± 354.6)
Median	28.9	35.9	Median		
				288.0	283.5
Peritoneal clearance:			Mean serum ferritin concentration		
Mean (± SD)**	50.3 (± 14.4)	47.9 (± 13.3)	≥ 100 ng/mL		
Median	49.6	47.2		638 (84)	460 (85)
Mean weekly creatinine clearance			Mean serum ferritin concentration		
≥ 60 L/wk/1.73m <sup>2</sup>	427 (63)	285 (64)	> 800 ng/mL		
				88 (12)	69 (13)
% anuric	266 (39)	163 (34)	Patients with relative iron deficiency <sup>c</sup>		
				37 (5)	24 (4)
<i>Anemia Management</i>			Patients prescribed iron		
Hemoglobin (gm/dL)			Within this group:		
Mean (± SD)	11.8 (± 1.4)	11.8 (± 1.2)	Prescribed IV		
Median	11.8	11.8		159 (31)	105 (29)
Mean Hgb < 9	34 (4)	+	Prescribed PO		
Mean Hgb < 10	72 (9)	36 (7)		406 (78)	292 (81)
Mean Hgb 11-12.0 <sup>b</sup>	241 (35)	169 (35)	Serum Albumin (gm/dL)		
Mean Hgb ≥ 11	604 (77)	420 (76)	BCG <sup>d</sup>		
Patients prescribed Epoetin alfa			Mean (± SD)*		
	698 (89)	498 (90)		3.61 (± 0.48)	3.49 (± 0.48)
Within this group:			Median		
Prescribed IV	29 (4)	24 (5)		3.63	3.53
Prescribed SC	669 (98)	483 (98)	BCP <sup>e</sup>		
			Mean (± SD)***		
				3.32 (± 0.51)	3.11 (± 0.52)
			Median		
				3.30	3.07
			Mean serum albumin ≥ 4.0/3.7 gm/dL		
			(BCG/BCP)*		
				178 (23)	78 (14)
			Mean serum albumin ≥ 3.5/3.2 gm/dL		
			(BCG/BCP)*		
				509 (65)	300 (55)

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

+ Value suppressed because n < 11

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

<sup>b</sup> Among patients prescribed Epoetin alfa

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

<sup>d</sup> BCG – bromocresol green laboratory method

<sup>e</sup> BCP – bromocresol purple laboratory method

Table 3: Selected intermediate outcomes by diabetes category, within subset of patients with diabetes

Clinical Measure <sup>a</sup>	Diabetes, no meds (n=50)	Diabetes, meds (not insulin) (n=75)	Diabetes, insulin (n=428)	Clinical Measure <sup>a</sup>	Diabetes, no meds (n=50)	Diabetes, meds (not insulin) (n=75)	Diabetes, insulin (n=428)
<i>Adequacy of Dialysis</i>				Weekly Epoetin alfa dose (units/kg/week)			
Weekly Kt/V urea				IV			
Total clearance				Mean (± SD)	+	+	122.3 (± 72.7)
Mean (± SD)	2.37 (± 0.89)	2.33 (± 0.64)	2.36 (± 0.60)	Median	+	+	103.4
Median	2.10	2.20	2.29	SC			
Renal clearance:				Mean (± SD)	159.3 (± 98.4)	123.6 (± 92.2)	128.3 (± 82.1)
Mean (± SD)	1.01 (± 0.94)	0.74 (± 0.70)	0.84 (± 0.66)	Median	132.4	113.2	110.5
Median	0.62	0.54	0.65	Transferrin saturation (%)			
Peritoneal clearance:				Mean (± SD)	26.7 (± 10.1)	30.6 (± 11.7)	28.2 (± 10.3)
Mean (± SD)	1.74 (± 0.52)	1.86 (± 0.47)	1.82 (± 0.46)	Median	25.7	28.7	26.7
Median	1.72	1.85	1.79	Mean transferrin saturation			
Mean weekly Kt/V ≥ 2.0				≥ 20%	39 (83)	60 (85)	334 (81)
23 (61)	48 (74)	247 (70)		Serum ferritin concentration (ng/mL)			
Weekly creatinine clearance (L/wk/1.73m <sup>2</sup> )				Mean (± SD)	429.0 (± 350.5)	440.3 (± 393.2)	385.2 (± 348.0)
Total clearance:				Median	326.0	327.3	266.5
Mean (± SD)	70.1 (± 28.3)	73.1 (± 29.2)	76.6 (± 30.8)	Mean serum ferritin concentration			
Median	60.1	65.4	69.9	≥ 100 ng/mL	44 (94)	67 (91)	349 (84)
Renal clearance:				Mean serum ferritin concentration			
Mean (± SD)	50.4 (± 50.5)	43.0 (± 40.0)	51.4 (± 48.2)	> 800 ng/mL	+	+	52 (12)
Median	30.6	30.6	37.8	Patients with relative iron deficiency <sup>c</sup>			
Peritoneal clearance:				+	+		18 (4)
Mean (± SD)	45.8 (± 12.7)	48.8 (± 13.7)	48.0 (± 13.3)	Patients prescribed iron			
Median	46.4	46.5	47.4		31 (62)	48 (64)	283 (66)
Mean weekly creatinine clearance				Within this group:			
≥ 60 L/wk/1.73m <sup>2</sup>	18 (50)	40 (62)	227 (65)	Prescribed IV	12 (39)	13 (27)	80 (28)
% anuric	13 (33)	26 (39)	124 (33)	Prescribed PO	28 (90)	40 (83)	224 (79)
<i>Anemia Management</i>				<i>Serum Albumin (gm/dL)</i>			
Hemoglobin (gm/dL)				BCG <sup>d</sup>			
Mean (± SD)	11.6 (± 1.3)	11.9 (± 1.2)	11.8 (± 1.2)	Mean (± SD) <sup>***</sup>	3.56 (± 0.49)	3.61 (± 0.38)	3.46 (± 0.48)
Median	11.5	11.9	11.8	Median	3.70	3.65	3.50
Mean Hgb < 9	+	+	+	BCP <sup>e</sup>			
Mean Hgb < 10	+	+	28 (7)	Mean (± SD)	+	+	3.15 (± 0.53)
Mean Hgb 11-12.0 <sup>b</sup>	13 (30)	25 (36)	131 (35)	Median	+	+	3.22
Mean Hgb ≥ 11	33 (66)	61 (81)	326 (76)	Mean serum albumin ≥ 4.0/3.7 gm/dL			
Patients prescribed Epoetin alfa				(BCG/BCP)	+	+	60 (14)
	45 (90)	69 (92)	384 (90)	Mean serum albumin ≥ 3.5/3.2 gm/dL			
Within this group:				(BCG/BCP) <sup>*</sup>	33 (67)	45 (62)	222 (52)
Prescribed IV	+	+	18 (5)				
Prescribed SC	41 (95)	69 (100)	373 (98)				

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

+ Value suppressed because n < 11

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

<sup>b</sup> Among patients prescribed Epoetin alfa

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

<sup>d</sup> BCG – bromocresol green laboratory method

<sup>e</sup> BCP – bromocresol purple laboratory method