

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

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INTRODUCTION

The purpose of the End-Stage Renal Disease (ESRD) Clinical Performance Measures (CPM) Project is to assist providers of ESRD services in the assessment of care provided to their 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 in-center hemodialysis (HD) patients in the U.S. aged ≥ 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 adult in-center HD patients (aged ≥ 18 years), stratified by ESRD Network, identified by the 18 ESRD Networks as alive and receiving HD on December 31, 2001.

Data Collection

During May 2002, a three-page HD data collection form was sent to each facility that had one or more selected HD patients aged ≥ 18 years dialyzing at that facility. Staff at the facility abstracted clinical information from the medical record for each selected patient who was receiving in-center HD during the months of October, November, and December 2001. 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 pre- and post-dialysis weight, pre- and post-dialysis blood urea nitrogen (BUN) values and dialysis session length to calculate Kt/V values, dialyzer KUF values, type of vascular access, blood pump flow rates, hemoglobin (Hgb) values, prescribed Epoetin alfa dose and route of administration, iron use and route of administration, transferrin saturation (TSAT) values, serum ferritin concentrations,

serum albumin values and the laboratory method used to determine them (bromcresol green [BCG] or bromcresol 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 from responses to the above two questions: 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. Single pool Kt/V values were calculated according to the Daugirdas II formula.¹ 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. 8.02² and SPSS for Windows, v. 10.0.³

RESULTS

8200/8399 (98%) patients in the sample had information regarding diabetic diagnosis reported. The percent of patients

with diabetes ranged from 41% to 59% across the 18 ESRD Networks, with Networks 9 (IL, IN, KY), 14 (TX), and 15 (AZ, CO, NM, NV, UT, WY) reporting the highest percentages (Figure 1). Within the group of patients with diabetic status

Figure 1: Distribution of in-center hemodialysis patients with diabetes in the U.S.

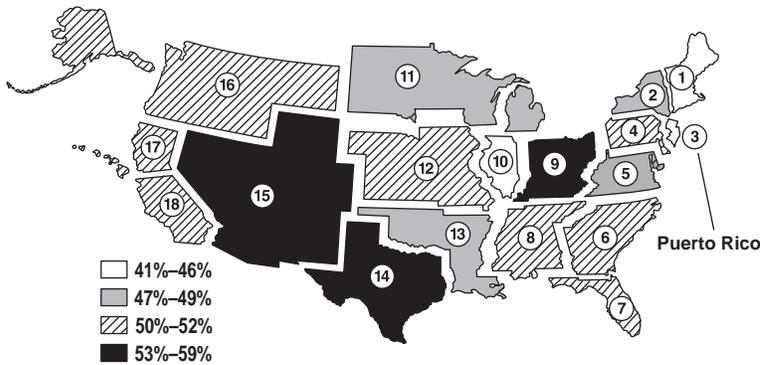


Table 1a: Selected patient characteristics by diabetes category

Patient Characteristic	No Diabetes (n=4128)	History of Diabetes (n=4072)
% Male*	57	48
Race		
% White	54	53
% Black	39	36
Ethnicity		
% Hispanic*	10	15
Age (years)		
Mean (± SD)*	59.2 (± 17.4)	63.5 (± 12.6)
Median	60.2	64.8
% 18-44 years*	25	9
% 45-64	33	42
% 65+*	43	49
% with diabetes mellitus as cause of ESRD [^] *	5	82
Duration of dialysis (years)		
Mean (± SD)*	4.4 (± 4.7)	2.8 (± 2.7)
Median	2.7	2.0
% with amputation(s) ^{^^} *	2	13
Post-dialysis BMI ^{^^^} (kg/m ²)		
Mean (± SD)*	25.4 (± 6.2)	28.2 (± 6.9)
Median	24.1	27.0

Note: Percents may not add up to 100% due to rounding. Significant difference among diabetic groups noted by: *p < 0.001

[^] Diabetes mellitus as cause of ESRD was derived from information on 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).

^{^^^} BMI – body mass index

reported, 4128 (50%) did not have diabetes, 1014 (12%) had diabetes but were not on medications to treat the diabetes, 736 (9%) had diabetes that was treated by medications, but not insulin, and 2322 (28%) had diabetes and were using insulin. Patients with diabetes were more likely to be female, Hispanic, older, have a higher mean body mass index (BMI – kg/m²) and an amputation(s), all p's < 0.001 (Table 1a). They were also more likely to have dialyzed fewer years than patients without diabetes (p < 0.001). Within the subset of patients with diabetes, those currently using insulin were more likely to be younger and have a higher mean BMI than patients with diabetes not currently using insulin, all p's < 0.001 (Table 1b).

Table 1b: Selected patient characteristics by diabetes category within subset of patients with diabetes

Patient Characteristic	Diabetes, no meds (n=1014)	Diabetes, meds (not insulin) (n=736)	Diabetes, insulin (n=2322)
% Male	48	50	47
Race			
% White*	45	56	56
% Black*	41	33	34
Ethnicity			
% Hispanic**	15	19	14
Age (years)			
Mean (± SD)*	65.3 (± 12.2)	65.9 (± 11.2)	61.9 (± 12.9)
Median	66.5	66.6	63.2
% 18-44 years*	6	4	12
% 45-64	39	39	44
% 65+*	55	57	44
% with diabetes mellitus as cause of ESRD [^] *	71	78	88
Duration of dialysis (years)			
Mean (± SD)*	3.1 (± 2.9)	2.4 (± 2.5)	2.8 (± 2.7)
Median	2.3	1.7	2.0
% with amputation(s) ^{^^} *	10	7	16
Post-dialysis BMI ^{^^^} (kg/m ²)			
Mean (± SD)*	27.4 (± 6.5)	28.0 (± 6.5)	28.5 (± 7.2)
Median	26.3	26.7	27.3

Note: Percents may not add up to 100% due to rounding. Significant difference among diabetic groups noted by: *p < 0.001; ** p < 0.01

[^] Diabetes mellitus as cause of ESRD was derived from information on 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).

^{^^^} BMI – body mass index

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

Adequacy of Dialysis

Patients with diabetes compared to patients without diabetes were more likely to have a lower mean Kt/V over the three-month study period (1.49 [± 0.26] vs. 1.51 [± 0.26], $p < 0.001$), and slightly fewer patients with diabetes had a mean Kt/V ≥ 1.2 (88% vs. 89%, $p < 0.05$). Similar results were noted for mean URR and URR $\geq 65\%$. Patients with diabetes tended to have longer dialysis session lengths, but similar blood pump flow rates and use of hi-flux dialyzers compared to patients without diabetes.

Vascular Access

Fewer patients with diabetes had an AV fistula as their vascular access compared to patients without diabetes (27% vs. 36%, $p < 0.001$), and were more likely to have an AV graft as their access (46% vs. 39%, $p < 0.001$). Catheter usage was similar for both groups, with approximately one-fourth of patients in both groups having a catheter as their access.

Anemia Management

The mean hemoglobin for patients with diabetes was slightly lower compared to patients without diabetes (11.6 [± 1.2] vs. 11.7 [± 1.2], $p < 0.05$). A slightly lower percent of patients with diabetes had a mean hemoglobin ≥ 11 gm/dL compared to patients without diabetes (75% vs. 77%, $p < 0.05$). These results are likely to be clinically insignificant. Patients with diabetes were prescribed lower mean Epoetin alfa doses by either the intravenous (IV) or subcutaneous (SC) route than patients without diabetes in achieving equivalent hemoglobin targets.

Patients with diabetes had lower mean transferrin saturation values (28.1% [± 11.7%] vs. 29.8% [± 12.8%], $p < 0.001$) and fewer had a mean transferrin saturation $\geq 20\%$ compared to patients without diabetes (78% vs. 81%, $p < 0.01$). There were no significant differences between groups in mean serum ferritin concentration values or in having a mean serum ferritin concentration ≥ 100 ng/mL or > 800 ng/mL.

Patients with diabetes were more likely to have iron prescribed than were patients without diabetes (69% vs. 65%, $p < 0.001$).

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 (BCG/BCP) (29% vs. 41%, $p < 0.001$) or 3.5/3.2 gm/dL (BCG/BCP) (78% vs. 86%, $p < 0.001$).

Within the Subset of Patients with Diabetes (Table 3)

Adequacy of Dialysis

Similar percentages of patients in all diabetic categories had a mean Kt/V ≥ 1.2 and a mean URR $\geq 65\%$. Patients with diabetes currently using insulin had slightly longer dialysis sessions compared to patients with diabetes on no medications for their diabetes and to patients with diabetes on medication, but not insulin to control their diabetes. Blood pump flow rates and dialyzer KUfs were similar across groups. Although dialysis session lengths were longer for patients with diabetes currently using insulin compared to patients in the other diabetic groups, the mean and median Kt/V values were not higher. Body size may have implications for dialysis adequacy for these groups of patients.

Vascular Access

AV fistula use was similar across groups. Patients with diabetes currently using insulin were more likely to have a catheter as their access compared to patients with diabetes on no medications for their diabetes and to patients with diabetes on medication, but not insulin to control their diabetes (28% vs. 25% and 24%, respectively, $p < 0.05$). They were also less likely to have an AV graft as their access (44% vs. 49% and 48%, $p < 0.05$).

Anemia Management

There were no significant differences in either mean hemoglobin or achieving hemoglobin thresholds by diabetic category. Similar Epoetin alfa doses were prescribed by either the IV or the SC route across diabetic categories.

Patients with diabetes currently using insulin had significantly lower transferrin saturation values compared to patients with diabetes on no medications for their diabetes and to patients with diabetes on medication, but not insulin to control their diabetes, but similar percentages of patients in each group had a mean transferrin saturation $\geq 20\%$. There were no significant differences across diabetic categories in mean serum ferritin concentration values or in having a mean serum ferritin concentration ≥ 100 ng/mL or > 800 ng/mL.

Serum Albumin

Patients with diabetes currently using insulin had significantly lower mean serum albumin values by either the BCG or the BCP method compared to patients with diabetes on no medications for their diabetes and to patients with diabetes on medication, but not insulin to control their diabetes, and fewer achieved a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP) (27% vs. 34% and 30%, respectively, $p < 0.001$) or 3.5/3.2 gm/dL (BCG/BCP) (76% vs. 80% and 80%, respectively, $p < 0.01$).

Table 2: Selected intermediate outcomes by diabetic category

Clinical Measure ^a	No diabetes (n=4128)	History of Diabetes (n=4072)	Clinical Measure ^a	No diabetes (n=4128)	History of Diabetes (n=4072)
Clearance			Weekly Epoetin alfa dose (units/kg/week)		
Kt/V			IV		
Mean (± SD)*	1.51 (± 0.26)	1.49 (± 0.26)	Mean (± SD)*	267.1 (± 257.8)	239.0 (± 189.4)
Median	1.50	1.48	Median	204.2	190.3
Mean Kt/V ≥ 1.2***	3635 (89)	3524 (88)	SC		
URR (%)			Mean (± SD)**		
Mean (± SD)*	71.3 (± 6.8)	70.6 (± 6.7)	Median	233.7 (± 244.8)	193.9 (± 156.4)
Median	71.9	71.3	Transferrin saturation (%)		
Mean URR ≥ 65%*	3546 (86)	3375 (83)	Mean (± SD)*	29.8 (± 12.8)	28.1 (± 11.7)
Dialysis session length (minutes)			Median	27.3	26.0
Mean (± SD)*	213.9 (± 30.8)	219.1 (± 28.5)	Mean transferrin saturation		
Median	210.0	216.7	≥ 20%**	3158 (81)	3019 (78)
Blood pump flow rate (mL/minute)			Serum ferritin concentration (ng/mL)		
Mean (± SD)	397.3 (± 68.2)	395.7 (± 66.9)	Mean (± SD)	594.5 (± 418.3)	594.8 (± 418.8)
Median	400.0	400.0	Median	528.0	523.5
Dialyzed with a hi-flux dialyzer (KUF ≥ 20 mL/mmHg/hr)			Mean serum ferritin concentration		
2821 (80)	2856 (80)		≥ 100 ng/mL	3569 (91)	3540 (92)
Post-dialysis BMI (kg/m²)			Mean serum ferritin concentration		
Mean (± SD)*	25.4 (± 6.2)	28.2 (± 6.9)	> 800 ng/mL	1051 (27)	1053 (27)
Median	24.1	27.0	Patients with relative iron deficiency^c		
Vascular Access			Patients prescribed iron*		
Type of access			Within this group:		
AV fistula*	1476 (36)	1102 (27)	Prescribed IV**	2526 (94)	2702 (96)
AV graft*	1593 (39)	1860 (46)	Prescribed PO**	254 (10)	205 (7)
Catheter	1014 (25)	1068 (27)	Serum Albumin (gm/dL)		
Catheter in use ≥ 90 days	780 (19)	822 (20)	BCG^d		
Anemia Management			Mean (± SD)*		
Hemoglobin (gm/dL)			Median	3.86 (± 0.41)	3.74 (± 0.40)
Mean (± SD)***	11.7 (± 1.2)	11.6 (± 1.2)	BCP^e		
Median	11.8	11.7	Mean (± SD)*	3.66 (± 0.50)	3.52 (± 0.49)
Mean Hgb < 9	102 (3)	85 (2)	Median	3.67	3.53
Mean Hgb < 10	319 (8)	326 (8)	Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)*		
Mean Hgb 11-12.0 ^b	1519 (38)	1522 (39)		1703 (41)	1177 (29)
Mean Hgb ≥ 11***	3191 (77)	3052 (75)	Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP)*		
Patients prescribed Epoetin alfa**				3521 (86)	3151 (78)
	3941 (96)	3934 (97)			
Within this group:					
Prescribed IV	3602 (91)	3565 (91)			
Prescribed SC	373 (9)	392 (10)			

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

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

^b Among patients prescribed Epoetin alfa

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

^d BCG – bromocresol green laboratory method

^e BCP – bromocresol purple laboratory method

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

Clinical Measure ^a	Diabetes, no meds (n=1014)	Diabetes, meds (not insulin) (n=736)	Diabetes, insulin (n=2322)	Clinical Measure ^a	Diabetes, no meds (n=1014)	Diabetes, meds (not insulin) (n=736)	Diabetes, insulin (n=2322)
Clearance				Weekly Epoetin alfa dose (units/kg/week)			
Kt/V				IV			
Mean (± SD)***	1.50 (±0.27)	1.49 (±0.26)	1.48 (±0.25)	Mean (± SD)	240.0 (±185.8)	223.4 (±164.2)	243.3 (±197.9)
Median	1.49	1.49	1.48	Median	192.3	185.5	191.5
Mean Kt/V ≥ 1.2	878 (88)	637 (88)	2009 (88)	SC			
URR (%)				Mean (± SD)			
Mean (± SD)	70.9 (± 7.1)	70.8 (± 6.5)	70.4 (± 6.6)		210.3 (±164.7)	200.1 (±157.4)	184.9 (±152.4)
Median	71.7	71.5	71.0	Median	169.5	156.4	145.7
Mean URR ≥ 65%	850 (84)	619 (84)	1906 (82)	Transferrin saturation (%)			
Dialysis session length (minutes)				Mean (± SD)***			
Mean (± SD)**	218.0 (±28.2)	216.9 (±27.6)	220.3 (±28.8)		29.0 (±12.0)	28.1 (±11.6)	27.7 (±11.5)
Median	213.6	214.7	220.0	Median	27.0	26.2	25.3
Blood pump flow rate (mL/minute)				Mean transferrin saturation ≥ 20%			
Mean (± SD)	394.0 (±66.4)	396.5 (±70.3)	396.1 (±66.1)		765 (80)	550 (79)	1704 (77)
Median	400.0	400.0	400.0	Serum ferritin concentration (ng/mL)			
Dialyzed with a hi-flux dialyzer (Kuf ≥ 20 mL/mmHg/hr)				Mean (± SD)			
	706 (80)	526 (82)	1624 (80)		606.9 (±424.4)	601.1 (±421.4)	587.4 (± 415.6)
Post-dialysis BMI (kg/m²)				Median			
Mean (± SD)*	27.4 (±6.5)	28.0 (±6.5)	28.5 (± 7.2)		535.0	529.0	514.0
Median	26.3	26.7	27.3	Mean serum ferritin concentration ≥ 100 ng/mL			
Vascular Access				Mean serum ferritin concentration > 800 ng/mL			
Type of access				Patients with relative iron deficiency^c			
AV fistula	266 (26)	202 (28)	634 (27)		33 (3)	20 (3)	78 (4)
AV graft***	490 (49)	351 (48)	1019 (44)	Patients prescribed iron			
Catheter***	248 (25)	176 (24)	644 (28)		682 (67)	515 (70)	1609 (69)
Catheter in use ≥ 90 days	181 (18)	140 (19)	501 (22)	Within this group:			
Anemia Management				Prescribed IV			
Hemoglobin (gm/dL)				Prescribed PO			
Mean (± SD)	11.6 (±1.1)	11.6 (±1.2)	11.7 (±1.2)		654 (96)	500 (97)	1548 (96)
Median	11.7	11.7	11.7		53 (8)	29 (6)	123 (8)
Mean Hgb < 9	18 (2)	15 (2)	52 (2)	Serum Albumin (gm/dL)			
Mean Hgb < 10	87 (9)	62 (8)	177 (8)	BCG^d			
Mean Hgb 11-12.0 ^b	385 (39)	279 (40)	858 (38)	Mean (± SD)*	3.78 (±0.41)	3.77 (±0.37)	3.72 (±0.40)
Mean Hgb ≥ 11	767 (76)	550 (75)	1735 (75)	Median	3.85	3.80	3.77
Patients prescribed Epoetin alfa				BCP^e			
	977 (96)	702 (95)	2255 (97)	Mean (± SD)***	3.63 (±0.43)	3.51 (0.49)	3.48 (±0.51)
Within this group:				Median			
Prescribed IV	887 (91)	633 (90)	2045 (91)		3.60	3.53	3.50
Prescribed SC	95 (10)	72 (10)	225 (10)	Mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP)*			
Significant differences between groups noted by: * p < 0.001; ** p < 0.01; *** p < 0.05				Mean serum albumin ≥ 3.5/3.2 gm/dL (BCG/BCP)**			
^a Continuous variables displayed as the mean (± SD) and median values; categorical variables displayed as number and percent of available values				812 (80) 587 (80) 1752 (76)			
^b Among patients prescribed Epoetin alfa							
^c Relative iron deficiency defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL							
^d BCG – bromocresol green laboratory method							
^e BCP – bromocresol purple laboratory method							

KEY OBSERVATIONS

Patients with Diabetes Compared to Patients without Diabetes

- Patients with diabetes were more likely to be female, Hispanic, older, have dialyzed fewer years, have a higher mean post-dialysis BMI, and have an amputation(s), compared to patients without diabetes.
- Patients with diabetes compared to patients without diabetes were more likely to have a lower mean Kt/V over the three-month study period despite longer dialysis session lengths, but similar blood pump flow rates and use of high flux dialyzers.
- Patients with diabetes were less likely to have an AV fistula and more likely to have an AV graft compared to patients without diabetes. Catheter usage was similar for both groups, with approximately one-fourth of patients in both groups having a catheter as their access.
- 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 (BCG/BCP).

Within the Subset of Patients with Diabetes

- Patients currently using insulin were more likely to be younger and have a higher mean post-dialysis BMI than patients with diabetes not currently using insulin.
- Patients with diabetes currently using insulin were more likely to have a catheter as their access compared to patients with diabetes on no medications for their diabetes and to patients with diabetes on medication, but not insulin to control their diabetes. Patients with diabetes currently using insulin were also less likely to have an AV graft as their access compared to other patients with diabetes.
- Patients with diabetes currently using insulin had significantly lower mean serum albumin values by either the BCG or the BCP method compared to patients with diabetes on no medications for their diabetes and to patients with diabetes on medication, but not insulin to control their diabetes, and fewer achieved a mean serum albumin $\geq 4.0/3.7$ gm/dL (BCG/BCP).

NEXT STEPS

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

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