Has Dialysis Payment Reform Led to Initial Racial Disparities in Anemia and Mineral Metabolism Management?

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ABSTRACT

Implementation of the Medicare ESRD prospective payment system (PPS) and changes to dosing guidelines for erythropoiesis-stimulating agents (ESAs) in 2011 appear to have influenced use of injectable medications among dialysis patients. Given historically higher ESA and vitamin D use among black patients, we assessed the effect of these policy changes on racial disparities in the management of anemia and mineral metabolism. Analyses used cross-sectional monthly cohorts for a period-prevalent sample of 7384 maintenance hemodialysis patients at 132 facilities from the Dialysis Outcomes and Practice Patterns Study (DOPPS) Practice Monitor. Linear splines with knots at each policy change were used in survey-weighted regressions to estimate time trends in hemoglobin (Hgb), erythropoietin (EPO) dose, intravenous (IV) iron dose, ferritin, transferrin saturation (TSAT) concentration, parathyroid hormone (PTH), IV vitamin D dose, cinacalcet use, and phosphate binder use. From August 2010 to December 2011, mean Hgb declined from 11.5 to 11.0 g/dl ($P<0.001$), mean EPO dose declined from 20,506 to 14,777 U/wk ($P<0.001$), and mean serum PTH increased from 340 to 435 pg/ml ($P<0.001$). No meaningful differences by race were observed regarding the rates of change of management practices or laboratory measures (all $P>0.21$). Mean EPO and vitamin D dose and serum PTH levels remained higher in blacks. Despite evidence that anemia and mineral metabolism management practices have changed significantly over time, there was no immediate indication of racial disparities resulting from implementation of the PPS or ESA label change. Further studies are needed to examine effects among patient and facility subgroups.

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Implementation of the expanded Medicare ESRD prospective payment system (PPS) in January 2011 substantially altered financial incentives regarding injectable drugs and other services provided by dialysis facilities. Previously, outpatient dialysis was billed at a fixed rate, with intravenous (IV) medications billed separately on the basis of dose. Under the new PPS that was implemented by the Centers for Medicare & Medicaid Services (CMS), payment rates were established covering the cost of both outpatient dialysis as well as other dialysis services, including IV medications.[1] Among these, erythropoiesis-stimulating agents (ESAs) accounted for approximately 66% of the total estimated cost of services added to the bundle, followed by injectable vitamin D analogues (13%).[1]

In the absence of an adjustment for race, the changes resulting from this new payment policy may not be uniform for dialysis patients. A recent

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Table 1. Patient characteristics across several time points

Characteristic	August 2010 (*n*=3753)			January 2011 (*n*=4101)			June 2011 (*n*=4330)			December 2011 (*n*=4263)		
	Nonblack	Black	*P* Value	Nonblack	Black	*P* Value	Nonblack	Black	*P* Value	Non-Black	Black	*P* Value
Total patients, *n* (%)	2603 (69.4)	1150 (30.6)		2834 (69.1)	1267 (30.9)		2985 (68.9)	1345 (31.1)		2925 (68.6)	1338 (31.4)	
Male	1463 (55.9)	639 (56.0)	0.97	1569 (55.0)	698 (55.1)	0.97	1664 (55.6)	737 (54.8)	0.64	1623 (55.8)	747 (56.1)	0.85
Rural	632 (7.0)	245 (6.3)	0.78	785 (7.8)	275 (5.6)	0.30	804 (6.9)	271 (4.5)	0.18	769 (6.9)	283 (4.9)	0.25
Other race												
White	2268 (86.1)	–		2462 (85.8)	–		2578 (85.7)	–		2490 (84.7)	–	
Asian	170 (7.7)	–		181 (8.2)	–		181 (7.9)	–		183 (8.1)	–	
Native American	56 (1.6)	–		77 (1.4)	–		100 (1.4)	–		119 (1.9)	–	
Other	109 (4.7)	–		114 (4.6)	–		126 (4.9)	–		133 (5.3)	–	
Ethnicity[a]												
Hispanic	243 (13.3)	13 (1.7)	0.0002	300 (16.3)	18 (2.2)	<0.0001	325 (16.8)	19 (2.2)	0.0004	300 (16.5)	18 (1.6)	<0.0001
Non-Hispanic	2066 (85.1)	1018 (97.6)		2172 (81.2)	1098 (97.6)		2313 (82.0)	1187 (97.2)		2230 (82.5)	1174 (97.6)	
Unknown	28 (1.6)	6 (0.7)		28 (1.9)	4 (0.3)		27 (1.2)	5 (0.7)		16 (1.1)	4 (0.8)	
Region												
Central	718 (27.4)	202 (21.0)	0.34	713 (24.0)	190 (18.1)	0.13	806 (26.5)	234 (20.9)	0.16	741 (24.5)	226 (20.9)	0.09
East	817 (29.8)	459 (42.3)		1032 (35.5)	552 (47.1)		1037 (35.9)	577 (47.6)		1003 (35.6)	571 (47.4)	
South	496 (18.8)	322 (21.4)		456 (14.6)	456 (14.6)		444 (13.4)	361 (18.7)		452 (13.1)	376 (19.2)	
West	572 (24.0)	167 (15.3)		633 (25.9)	633 (25.9)		698 (24.3)	173 (12.8)		729 (26.8)	165 (12.4)	
Dialysis organization type												
Large dialysis organization	2097 (80.9)	1020 (90.7)	0.09	2202 (82.2)	1124 (91.7)	0.08	2276 (83.0)	1214 (90.7)	0.26	2227 (83.4)	1205 (90.7)	0.34
Medium dialysis organization	191 (7.4)	17 (1.0)		153 (5.6)	23 (1.3)		186 (4.3)	38 (3.5)		197 (5.5)	41 (4.4)	
Independent/small (≤10 facilities)	231 (9.3)	88 (6.7)		259 (9.7)	91 (6.3)		276 (9.9)	89 (5.7)		285 (8.4)	88 (4.8)	
Hospital-based	84 (2.4)	25 (1.6)		220 (2.5)	29 (0.7)		247 (2.8)	4 (0.1)		216 (2.6)	4 (0.1)	
Insurance[a]												
Medicare only	151 (6.9)	123 (9.9)	0.0003	154 (5.9)	126 (8.6)	<0.0001	176 (6.4)	149 (11.9)	<0.0001	187 (8.5)	151 (11.8)	<0.0001
Medicare primary and private/other	1103 (48.5)	385 (39.2)		1147 (47.9)	406 (38.5)		1175 (44.3)	420 (33.0)		1079 (42.5)	382 (32.7)	
Medicare and Medicaid	490 (18.9)	279 (26.6)		537 (18.9)	303 (28.8)		571 (19.4)	318 (29.2)		518 (18.2)	313 (27.5)	
Private primary	409 (19.3)	147 (15.9)		500 (22.3)	180 (17.3)		555 (23.5)	213 (18.6)		582 (24.8)	235 (20.1)	
Medicaid only	67 (2.4)	61 (5.2)		78 (2.7)	74 (5.1)		99 (3.1)	71 (4.6)		101 (3.3)	72 (5.2)	
Other/unknown	117 (4.1)	42 (3.2)		84 (2.4)	31 (1.8)		89 (3.2)	40 (2.7)		79 (2.7)	43 (2.6)	
ESRD cause[a]												
Diabetes	999 (42.3)	368 (34.6)	<0.0001	1051 (41.3)	389 (32.4)	<0.0001	1140 (41.4)	430 (35.0)	<0.0001	1124 (43.6)	427 (34.5)	<0.0001
GN	196 (8.6)	98 (9.7)		213 (9.0)	105 (9.3)		227 (9.0)	109 (8.8)		209 (8.8)	107 (9.3)	
Secondary GN/vasculitis	31 (1.3)	16 (1.2)		40 (1.5)	19 (1.6)		48 (1.9)	21 (1.4)		42 (1.6)	17 (1.0)	
Interstitial nephritis/ pyelonephritis	79 (3.0)	9 (0.8)		77 (2.6)	11 (1.3)		88 (3.3)	14 (1.3)		77 (3.0)	10 (1.0)	
Hypertension/large vessel disease	622 (26.6)	435 (42.4)		661 (27.0)	455 (41.0)		663 (25.4)	494 (41.3)		651 (25.5)	507 (43.1)	
Cystic/hereditary/congenital diseases	99 (4.3)	16 (0.9)		105 (4.2)	23 (2.0)		115 (4.2)	25 (1.8)		99 (3.6)	24 (1.6)	

Table 1. Continued

Characteristic	August 2010 (*n*=3753)			January 2011 (*n*=4101)			June 2011 (*n*=4330)			December 2011 (*n*=4263)		
	Nonblack	Black	*P* Value	Nonblack	Black	*P* Value	Nonblack	Black	*P* Value	Non-Black	Black	*P* Value
Neoplasms/tumors	53 (2.1)	18 (1.5)		60 (1.9)	18 (1.3)		61 (1.8)	19 (1.3)		64 (2.2)	17 (1.4)	
Other[b]	163 (6.5)	56 (6.1)		180 (7.9)	77 (8.5)		187 (6.9)	76 (7.0)		175 (6.9)	73 (6.9)	
Missing	95 (5.4)	21 (2.8)		113 (4.5)	23 (2.6)		136 (6.1)	23 (2.1)		105 (4.7)	14 (1.2)	
Mean values±SEM												
Age (yr)	65.7±0.57	59.1±0.45	<0.0001	65.8±0.63	58.8±0.47	<0.0001	65.4±0.58	59.0±0.54	<0.0001	64.8 (0.56)	59.4 (0.53)	<0.0001
Time since initiation of dialysis (yr)[c]	3.6±0.17	4.5±0.13	<0.0001	3.7±0.17	4.8±0.14	<0.0001	3.7±0.16	4.8±0.16	<0.0001	3.9 (0.16)	4.9 (0.14)	<0.0001
Kt/V[d]	1.6±0.01	1.5±0.01	<0.0001	1.6±0.01	1.5±0.01	<0.0001	1.6±0.02	1.5±0.02	<0.0001	1.6 (0.02)	1.6 (0.01)	<0.0001
Predialysis weight (kg)[e]	81.6±1.1	86.3±1.1	<0.0001	81.9±0.89	85.8±1.1	<0.0001	81.6±0.89	86.0±0.89	<0.0001	81.6 (0.88)	86.6 (0.88)	<0.0001

GN, glomerulonephritis; SEM, standard error of the mean.
[a]Calculated on a subset of the population.
[b]Miscellaneous conditions include sickle cell disease, post-partum renal failure, AIDS nephropathy, traumatic or surgical loss of kidney, hepatorenal syndrome, tubular necrosis, or uncertain etiology.
[c]Missing data: <1% for both blacks and nonblacks for all time points.
[d]Calculated only for patients on dialysis for at least 1 year who underwent dialysis 3 times per week.
[e]Missing data range: 11.6%–13.7% for blacks; 13.3%–16.6% for nonblacks.

analysis found average monthly expenditures for bundled services were 21% higher among black dialysis patients than patients of other racial groups, largely reflecting differences in the use of ESAs and certain other injectable medications.[2] These differences are consistent with disparate treatment needs, as historically, black dialysis patients have been shown to require higher ESA doses to achieve recommended hemoglobin (Hgb) targets and receive higher doses of vitamin D receptor analogues to manage mineral metabolism.[3–6] Thus, the introduction of financial disincentives regarding use of these medications under the expanded bundle may pose greater risks for black dialysis patients compared with other race groups.

Another important development related to anemia management in patients with ESRD involved the US Food and Drug Administration (FDA)–approved label change for ESAs, published in June 2011, which generally recommended more conservative ESA use.[7] Specifically, the new label replaced a target Hgb range of 10–12 g/dl with guidance to consider initiating ESA therapy at Hgb level<10 g/dl, to individualize dosing, and to use the lowest dose sufficient to limit the need for red blood cell transfusions.[7] Given the historical differences in ESA treatment patterns noted above, it is possible the response to changes in the ESA label will affect patients differentially by race.

The early effects of these payment and regulatory changes on the use of ESAs and other injectable medications, as well as laboratory findings, have been described.[8,9] The purpose of this study was to examine whether use of medications and laboratory measures related to anemia and mineral metabolism have changed differently for black dialysis patients compared with patients of other races.

RESULTS

Analyses used cross-sectional monthly cohorts for a period-prevalent sample of 7384 patients undergoing maintenance hemodialysis at 132 facilities from the Dialysis Outcomes and Practice Patterns Study (DOPPS) Practice Monitor (DPM). Patient demographic and clinical characteristics are described in Table 1. Point prevalent cohorts were examined and compared for August 2010, January 2011, June 2011, and December 2011. Overall, black patients made up approximately 31% of patients in each cohort. Compared with nonblack patients, black patients were younger, had been on dialysis longer, and had a higher average predialysis weight. The most prevalent cause of ESRD was hypertension among black patients and diabetes among nonblack patients. Additionally, a higher percentage of black patients resided in the East and South, received treatment from large dialysis organizations (LDOs), and were insured solely by Medicare or Medicaid. Black patients were also slightly less likely to be in rural settings. These differences between black and nonblack patients were consistent across all four time points (Table 1).

Table 2. Anemia measurements by race across several time points

Outcome	August 2010 (*n*=3753)		January 2011 (*n*=4101)		June 2011 (*n*=4330)		December 2011 (*n*=4263)		*P* Value for Change in Difference by Race from August 2010 to December 2011
	Nonblack	Black	Nonblack	Black	Nonblack	Black	Nonblack	Black	
Hgb (g/dl)	11.5	11.5	11.4	11.3	11.4	11.4	11.0	11.1	0.43
Patients with Hgb<9 g/dl (%)	2.8	3.3	2.5	3.4	2.7	2.9	3.8	6.7[a]	0.17
Patients with Hgb<10 g/dl (%)	8.5	9.3	8.8	10.5	9.0	9.1	16.1	16.8	0.92
Patients with Hgb>12 g/dl (%)	27.4	29.9	24.5	23.9	23.6	26.6	16.2	20.9	0.43
Patients with ESA use (%)	86.9	84.9	79.5	78.3	79.8	79.4	75.9	76.2	0.75
Prescribed IV EPO dose (U/wk)	19,737	22,104[b]	18,717	20,676	17,480	19,307	14,307	15,568	0.83
Patients with prescribed IV EPO dose ≥30,000 U/wk (%)	20.4	23.3	18.5	21.4	14.7	19.6[a]	12.4	12.3	0.21
Delivered IV EPO dose (U/wk)[c]	19,916	21,397	16,234	18,252[b]	16,735	17,791	13,233	14,304	0.70
Patients with IV iron use (%)	55.5	56.1	62.5	62.5	70.4	71.9	60.7	68.3[a]	0.04
Prescribed IV iron dose (mg/mo)	352	312[b]	394	361	367	357	351	325	0.76
Delivered IV iron dose (mg/mo)[d]	336	309	349	325	394	342[b]	354	333	0.59
Ferritin (ng/ml)	597	639	647	690	644	672	759	787	0.97
Patients with ferritin ≥800 ng/ml (%)	24.4	29.7	31.3	34.6	30.7	30.6	41.0	43.1	0.61
Patients with ferritin ≥1200 ng/ml (%)	6.1	7.0	6.9	8.2	8.5	9.7	14.3	13.5	0.69
TSAT (%)	30.3	31.3	30.5	31.1	30.8	31.3	31.6	31.8	0.88
Patients with TSAT ≥50% (%)	8.5	7.7	9.5	8.7	8.9	9.0	8.7	8.7	0.90

TSAT, transferrin saturation.
[a]Time point difference in black and nonblack: $0.01<P\leq0.05$.
[b]Time point difference in black and nonblack: $0.05<P\leq0.1$.
[c]Based on LDOs and a subset of non-LDOs.
[d]Based on a subset of facilities for which data were available.

Characteristics of the point-prevalent monthly cohorts of black and nonblack patients were tested statistically for changes over time. Cohort size increased over time, primarily because of the ongoing recruitment of additional DOPPS facilities. Characteristics of each cohort did not change substantially over time.

Time-Point Analyses: Anemia Management Measures

Cross-sectional summary means and proportions related to anemia management measures for the four key transitional time points are presented in Table 2. Mean Hgb levels were fairly stable at 11.4–11.5 g/dl across the first three time points, with a noticeable decrease to 11.0 g/dl apparent among all patients at the final time point (December 2011). In tandem, an increase in Hgb<10 g/dl from 8.7% at baseline to 16.3% at the final time point was also noted. An examination of Hgb<9 g/dl revealed a similar overall pattern. ESA use decreased similarly across time points for black and nonblack patients. The percentage of patients prescribed erythropoietin (EPO) at a dose of ≥30,000 U/wk decreased across time points, ranging from 23.3% to 12.3% among black patients and from 20.4% to 12.4% among nonblack patients. Overall, EPO dose tended to be higher among black patients, with this difference remaining fairly consistent across time points.

The percentage of patients using IV iron over time increased, appearing to peak at the third time point. Levels were slightly higher among black patients, with the largest difference observed in December 2011 (68.3% versus 60.7%; $P=0.02$), leading to a finding that trends in IV iron use differed by race over time ($P=0.04$ in Table 2). Ferritin levels also increased over time among all patients. In contrast, transferrin saturation levels remained fairly stable. The observed trends in anemia management practices other than IV iron use and in associated laboratory measures did not differ by race (Table 2).

Despite substantial trends in anemia management practices and associated laboratory measures over time, the only measure for which the observed trends differed by race involved IV iron use. No other evidence suggested that racial differences expanded or decreased between August 2010 and December 2011 (all other $P>0.15$ in Table 2). Results were similar according to a sensitivity analysis of trends by race in average ESA doses that incorporated IV EPO and estimated equivalencies for darbepoetin and subcutaneous ESA administration.

To consider potential confounding related to the inclusion of other race/ethnicity groups, we performed analyses that limited comparisons to black and white race groups while excluding Hispanic patients (not shown). Overall, among non-Hispanics, the trends for black versus white patients were similar to those presented in Table 2, with the exception of an observed decrease in prescribed EPO doses of ≥30,000 U/wk for black versus white patients that reached statistical significance (P=0.05).

We also explored the potential for racial disparities specific to younger patients, given previous findings of poorer outcomes for younger black dialysis patients.[10] Analyses stratified by age (<50, ≥50 years) indicated no statistically significant changes over time by race in anemia measures, with the exception of increasing IV iron use among black versus nonblack patients at older ages. For the younger age group, Hgb<10 and Hgb<9 g/dl occurred more frequently among black versus nonblack patients across the four time points (P=0.04 in both cases).

Time-Point Analyses: Measures of Mineral Metabolism Management

Differences between black and nonblack patients were statistically significant at each time point for all measures of mineral metabolism management except percentage of phosphate binder use (Table 3). The percentage of patients with serum parathyroid hormone (PTH)>600 pg/ml increased over time, ranging from 17.0% to 25.4% among black patients and from 8.8% to 15.1% among nonblack patients, with the largest increase between the first and second time points. This pattern was also seen in mean serum PTH levels. Percentage of IV vitamin D use remained relatively stable over time. For all measures of mineral metabolism management, there were no statistically significant changes over time in the magnitude of the difference between racial groups. Results were similar when we compared black and white groups among non-Hispanic patients and when stratifying analyses by age group (not shown).

Regression Analyses

Regression model results for anemia and measures of mineral metabolism management, expressed as adjusted race-specific trends by time period, are presented in Tables 4 and 5, respectively. On the basis of tests for each of these measures, which yielded the P values shown in the last column of the table, no statistically significant changes by race were seen across the three time periods. Overall time trends observed in the time-point analyses were supported by results from the regression models. For example, declines in mean Hgb levels among both black and nonblack patients were observed, which seem to align with key time points for policy changes implemented during these periods (Figure 1A). Corresponding patterns can be seen with prescribed EPO dose (Figure 1B). With respect to percentage of IV iron use (Figure 1C), an increasing trend can be observed during the first two time periods among both blacks and nonblacks, followed by stabilization among blacks and a slight decrease among nonblacks (P=0.24). Mean serum PTH increased during the pre-PPS period, followed by a stable leveling off after implementation of the PPS (Figure 1D). These trends are mirrored by the percentage of patients with serum PTH>600 pg/ml. Although the absolute increases seen here may have been modestly steeper among black patients, there did not appear to be a change in the relative level of difference between race groups over time.

The observed patterns in anemia and measures of mineral metabolism management did not change after further controlling for patient ethnicity, type of insurance coverage at baseline, number of years since initiation of dialysis, dialysis organization type, and facility urban or rural location (not shown). Results were also similar when we compared black and white groups among non-Hispanic patients (not shown).

DISCUSSION

This study of a national stratified random sample of dialysis facilities indicates that recent changes in clinical practices and laboratory measures related to the treatment of anemia and mineral metabolism have not differed markedly for black dialysis patients and patients of other race groups. There has been a key shift from financial incentives to disincentives for using injectable drugs to treat anemia and mineral metabolism

Table 3. Mineral metabolism measurements by race across several time points

Outcome	August 2010 (n=3753)		January 2011 (n=4101)		December 2011 (n=4263)		P Value for Change in Difference by Race (Black/Nonblack) from August 2010 to December 2011
	Nonblack	Black	Nonblack	Black	Nonblack	Black	
PTH (pg/ml)	305	417[a]	358	501[a]	388	522[a]	0.31
Patients with PTH >600 pg/ml (%)	8.8	17.0[a]	13.4	23.9[a]	15.1	25.4[a]	0.55
Patients with IV vitamin D use (%)	69.4	83.0[a]	66.7	84.2[a]	70.7	84.5[a]	0.20
Prescribed vitamin D dose (μg/wk)	11.7	18.7[a]	13.4	21.3[a]	15.3	22.7[a]	0.59
Delivered vitamin D dose (μg/wk)[b]	11.2	18.2[a]	13.0	22.3[a]	16.1	24.1[a]	0.10
Patients with cinacalcet use (%)	18.4	29.1[a]	17.8	31.4[a]	18.3	30.2[a]	0.44
Patients with phosphate binder use (%)	77.3	79.1	74.5	78.9	76.8	82.0	0.54

[a]Time point difference in black and nonblack: 0<P≤0.01.
[b]Based on a subset of facilities for which data were available.

Table 4. Adjusted change in anemia measurements for black and nonblack patients across three time periods

Outcome	Monthly Δ (95% CI): August 2010–December 2010 Pre-PPS		Monthly Δ (95% CI): January 2011–June 2011 Post-PPS/ Pre-ESA Label Change		Monthly Δ (95% CI): July 2011–December 2011 Post-ESA Label Change		*P* Value for Difference in Trends by Race
	Nonblack	Black	Nonblack	Black	Nonblack	Black	
Hgb (g/dl)	0.02 (−0.04 to 0.01)	−0.04 (−0.08 to 0.00)	−0.01 (−0.02 to 0.01)	−0.00 (−0.02 to 0.02)	−0.07 (−0.09 to −0.05)	−0.06 (−0.11 to −0.02)	0.63
Patients with Hgb <9 g/dl (%)	−0.04 (−0.27 to 0.19)	0.04 (−0.35 to 0.42)	0.04 (−0.11 to 0.18)	−0.07 (−0.32 to 0.19)	0.19 (0.02 to 0.36)	0.62 (0.15 to 1.10)	0.37
Patients with Hgb <10 g/dl (%)	0.03 (−0.36 to 0.43)	0.45 (−0.34 to 1.23)	−0.01 (−0.32 to 0.30)	−0.23 (−0.81 to 0.34)	1.24 (0.83 to 1.66)	1.64 (0.68 to 2.59)	0.64
Patients with Hgb >12 g/dl (%)	−0.63 (−1.44 to 0.18)	−1.57 (−2.84 to −0.30)	−0.47 (−0.95 to 0.02)	−0.26 (−0.90 to 0.38)	−1.35 (−1.92 to −0.79)	−0.70 (−2.01 to 0.61)	0.39
Patients with ESA use (%)	−1.40 (−1.98 to −0.81)	−1.57 (−2.53 to −0.61)	−0.41 (−0.95 to 0.13)	0.15 (−0.34 to 0.65)	−0.78 (−1.41 to −0.14)	−0.98 (−1.71 to −0.24)	0.40
Prescribed IV EPO dose (U/wk)	−160 (−566 to 246)	−353 (−831 to 124)	−224 (−448 to 0)	−278 (−541 to −15)	−647 (−838 to −457)	−648 (−930 to −366)	0.74
Patients with prescribed IV EPO dose≥30,000 U/wk (%)	−0.29 (−1.31 to 0.73)	−0.56 (−1.69 to 0.56)	−0.66 (−1.10 to −0.21)	−0.46 (−0.97 to 0.06)	−0.66 (−1.03 to −0.28)	−1.34 (−2.12 to −0.57)	0.30
Delivered IV EPO dose (U/wk)[a]	−554 (−879 to −229)	−500 (−858 to −142)	−108 (−310 to 95)	−91 (−306 to 125)	−639 (−842 to −436)	−705 (−1021 to −390)	0.98
Patients with IV iron use (%)	1.69 (0.26 to 3.11)	1.52 (−0.26 to 3.31)	1.14 (0.08 to 2.19)	1.40 (−0.33 to 3.14)	−1.79 (−2.63 to −0.94)	−0.84 (−1.84 to 0.15)	0.23
Prescribed IV Iron dose (mg/mo)	10.20 (1.94 to 18.47)	6.81 (−4.90 to 18.53)	−7.98 (−17.75 to 1.79)	−3.23 (−14.21 to 7.74)	−1.76 (−5.32 to 1.80)	−2.35 (−7.88 to 3.18)	0.84
Delivered IV iron dose (mg/mo)[b]	4.05 (−4.68 to 12.77)	5.61 (−2.90 to 14.12)	1.72 (−6.44 to 9.88)	4.43 (−5.55 to 14.40)	−3.43 (−7.79 to 0.93)	−3.66 (−9.68 to 2.36)	0.84
Ferritin (ng/ml)	8.96 (0.53 to 17.38)	7.07 (−5.89 to 20.03)	2.02 (−3.55 to 7.58)	2.05 (−6.30 to 10.40)	19.79 (13.82 to 25.75)	23.83 (16.31 to 31.35)	0.74
Patients with ferritin ≥800 ng/ml (%)	0.99 (0.10 to 1.89)	0.57 (−0.86 to 2.01)	0.29 (−0.38 to 0.95)	−0.15 (−1.19 to 0.89)	1.93 (1.23 to 2.63)	2.50 (1.78 to 3.22)	0.43
Patients with ferritin ≥1200 ng/ml (%)	0.21 (−0.37 to 0.79)	0.15 (−0.70 to 1.00)	0.19 (−0.09 to 0.48)	0.60 (−0.05 to 1.25)	1.08 (0.72 to 1.44)	0.88 (0.25 to 1.51)	0.67
TSAT (%)	−0.07 (−0.31 to 0.17)	−0.05 (−0.37 to 0.27)	0.24 (0.05 to 0.42)	0.16 (−0.10 to 0.43)	0.10 (−0.07 to 0.28)	0.12 (−0.09 to 0.33)	0.97
Patients with TSAT ≥50% (%)	0.14 (−0.21 to 0.49)	0.04 (−0.55 to 0.63)	0.09 (−0.23 to 0.42)	0.18 (−0.26 to 0.62)	0.01 (−0.28 to 0.29)	0.17 (−0.21 to 0.56)	0.50

Models adjusted for age, sex, predialysis weight, years since dialysis initiation, geographic region, and ESRD cause. 95% CI, 95% confidence interval; TSAT, transferrin saturation.

[a]Based on LDOs and a subset of non-LDOs.

[b]Based on a subset of facilities for which data were available.

Table 5. Adjusted change in mineral metabolism measurements for black and nonblack patients across two time periods

Outcome	Pre-PPS: Monthly Δ (95% CI), August 2010–December 2010		Post-PPS: Monthly Δ (95% CI), January 2011–December 2011 Post-PPS		*P* Value Difference in Trends by Race
	Nonblack	Black	Nonblack	Black	
PTH (pg/ml)	13.15 (8.99 to 17.31)	18.31 (8.01 to 28.60)	1.14 (−1.27 to 3.56)	1.11 (−2.53 to 4.76)	0.59
Patients with PTH >600 pg/ml (%)	0.93 (0.35 to 1.50)	1.61 (0.63 to 2.58)	0.17 (−0.04 to 0.39)	−0.00 (−0.33 to 0.33)	0.39
Patients with IV vitamin D use (%)	−0.70 (−1.47 to 0.06)	0.26 (−0.59 to 1.11)	0.38 (0.10 to 0.66)	0.23 (−0.07 to 0.53)	0.22
Prescribed vitamin D dose (μg/wk)	0.46 (0.12 to 0.81)	0.74 (−0.01 to 1.49)	0.21 (0.06 to 0.36)	0.13 (−0.10 to 0.36)	0.53
Delivered vitamin D dose (μg/wk)[a]	0.48 (0.06 to 0.90)	1.17 (0.16 to 2.17)	0.26 (0.08 to 0.44)	0.18 (−0.02 to 0.38)	0.28
Patients with cinacalcet use (%)	−0.18 (−0.74 to 0.38)	−0.21 (−0.95 to 0.54)	0.04 (−0.20 to 0.29)	0.08 (−0.34 to 0.50)	0.99
Patients with phosphate binder use (%)	−0.94 (−1.62 to −0.25)	−0.66 (−1.78 to 0.45)	0.26 (−0.11 to 0.63)	0.36 (−0.09 to 0.80)	0.83

Models adjusted for age, sex, predialysis weight, years since dialysis initiation, geographic region, and ESRD cause. 95% CI, 95% confidence interval.
[a]Based on a subset of facilities for which data were available.

under the bundled payment system which, coupled with prior evidence of higher drug utilization and costs for treating these conditions in black patients, might suggest a risk for growing racial disparities in care, as postulated by the US Government Accountability Office in their 2010 report.[3] In the context of anemia management, the FDA-approved ESA label modification appears to have led to even larger changes in practice, as suggested by the relatively steep declines in EPO doses and Hgb levels starting in mid-2011. There may also have been changes in anemia management practices during 2011 that reflect anticipation of the implementation of the CMS Quality Incentive Program in 2012, which established payment reductions for Hgb values >12 g/dl or <10 g/dl. However, our data do not indicate differential effects of these policy and regulatory changes by race during this period. Consistent with recent reports of post-PPS implementation changes in anemia management, our results indicate declining ESA use paired with increasing IV iron use.[9,11] Changes in practice appeared to begin during the pre-PPS period (August–December 2010), perhaps in anticipation of the new payment system. The period immediately following the ESA label change corresponded with steeper declines in ESA use and a stabilization or possible slight decrease in IV iron use. The resulting decreases in ESA use have occurred on a similar scale by race, such that the higher EPO doses among black patients compared with patients of other races appear to have continued following these recent policy and regulatory changes. Although achieved Hgb levels declined during the study period, they also remained relatively similar by race. These findings are consistent with prior studies suggesting that black patients require higher ESA doses, on average, to achieve similar Hgb outcomes.[4–6]

Patterns by race in both the use of medications and laboratory measures related to mineral metabolism also appeared to be relatively similar after the payment reform. This includes greater use of injectable vitamin D products and cinacalcet, as well as higher PTH levels, among black dialysis patients before and during 2011. This is consistent with historical reports of racial differences in clinical patterns.[2,12] The recent increase in PTH levels could be partly related to the 2009 Kidney Disease Improving Global Outcomes guidelines that raised the upper PTH target to nine times the assay's upper limit of normal (roughly 500–600 pg/ml).[13] Because increased PTH levels have been associated with higher mortality risk,[14–17] the increased number of black patients with very high PTH levels may have implications for relative mortality outcomes by race, which merits additional study. As observed with anemia management, it appears there were significant changes in practice related to management of mineral metabolism, likely due to the combined effects of the PPS and other factors, including updates to clinical practice guidelines. The evidence does not suggest, however, that these changes have affected patients differentially by race.

The broader context in which the bundle was implemented in 2011, which was also affected by key contemporaneous scientific and regulatory developments, might suggest caution in concluding that the ESRD payment reform will not contribute to future racial disparities in care. The results of recent clinical trials related to anemia in CKD and, in particular, the June 2011 change in the ESA label, appear to have lowered target Hgb levels and prompted a less aggressive clinical approach for using ESAs to treat anemia.[7,18–20] Additionally, whereas the Quality Incentive Program penalized Medicare dialysis facility payments in 2012 on the basis of the percentage of patients with Hgb values outside the range of 10–12 g/dl, 2013 payment penalties (based on 2011 performance) were only incurred if Hgb values exceeded 12 g/dl.[21] This policy change may have further contributed to modifications in anemia management practices. Our study indicates that the largest decline in EPO doses and Hgb levels occurred directly after the June 2011

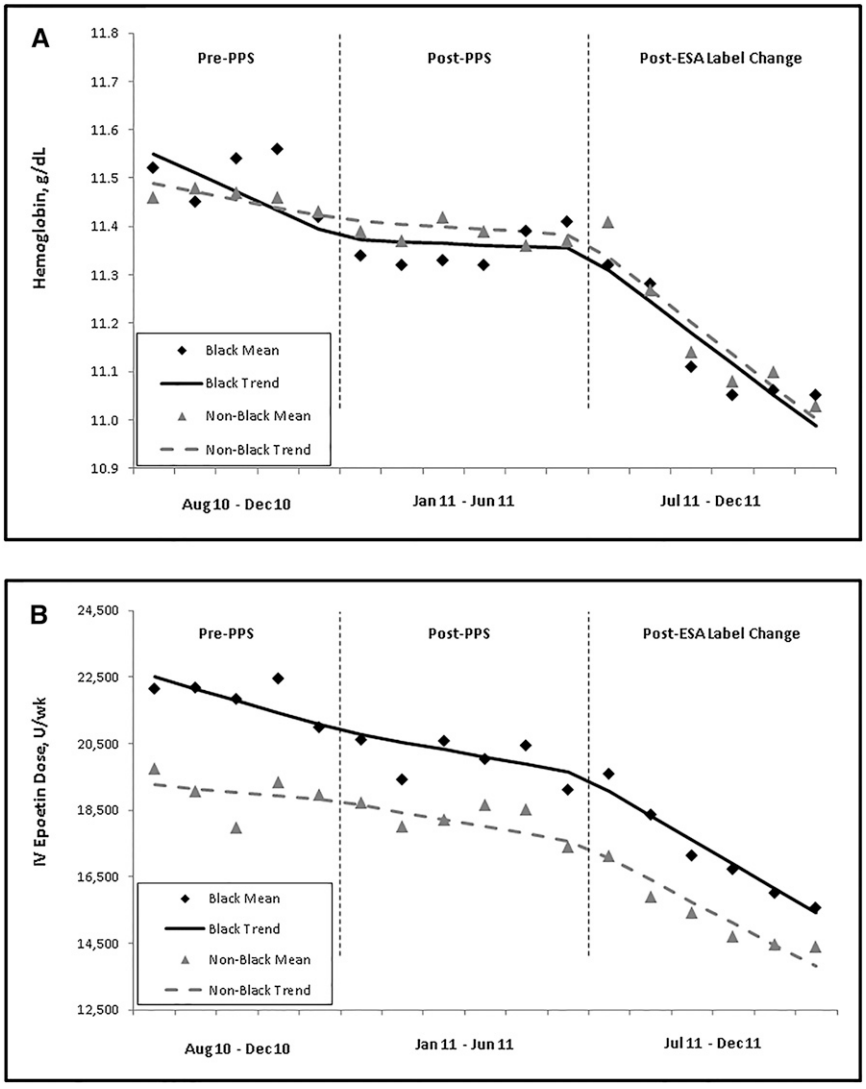

Figure 1. (A) Similar declines in Hgb over time for black and non-black patients. (B) Similar declines in prescribed IV epoetin dose over time for black and non-black patients. Figure 1 Continued.

ESA label change, which had not been anticipated when the initial base payment rate for the bundle was established.[1] The label change may have, in a sense, alleviated the financial pressures on dialysis facilities under the bundled payment system. However, on the basis of a recent adjustment to the bundled Medicare payment rate to reflect declining utilization of ESAs and other injectable drugs, and the planned expansion of the bundle to include oral-only ESRD medications, it will be important to consider the potential for disparities in care in the context of any future changes to the bundled payment system.

This study has potential limitations which should be noted and considered for further research. First, despite the absence of overall diverging trends in care by race, we did not examine whether there may be disparities emerging for certain subgroups of black dialysis patients. For example, it may be important to consider the role of factors that could put certain dialysis facilities at a financial disadvantage under the bundled payment system and may limit their ability to manage the higher costs of treating certain patient populations. Preliminary findings from the Study to Evaluate the Prospective Payment System Impact on Small Dialysis Organizations (STEPPS) suggest that changes in anemia management may have been more pronounced for black patients among small facilities.[11] However, this study only examined trends through June 2011, before the FDA-approved ESA label change.

Second, this study focused largely on changing patterns related to medication use. We did not examine, for example, trends in red blood cell transfusions. Unlike ESAs, blood transfusions are not covered under the bundled payment system, potentially creating financial incentives that encourage greater use of blood transfusions to treat anemia. The use of blood transfusions poses a risk of allosensitization, predisposing the recipient to a positive crossmatch against a potential donor allograft which would eliminate the patient as an immunologically appropriate recipient for the donor organ. This has been shown to lead to longer waiting list times and lower frequencies of transplantation.[22] Because increased blood transfusions among black dialysis patients relative to other race groups could further contribute to previously identified racial disparities in access to transplantation, this possibility should also be evaluated as a potential consequence of the bundled payment system.[22–26] A recent study of blood transfusions in Medicare dialysis patients did not find rates of transfusion were increasing for black patients compared with patients of other races starting in 2011, based on Medicare claims.[27] However, STEPPS did find evidence of increased transfusions among black patients.[11] Continued monitoring over a longer follow-up period is thus warranted, particularly among smaller facilities which have fewer patients over which to distribute variable costs of care.

As a limitation of the study data, delivered IV iron and vitamin D doses were only reported by facilities affiliated with LDOs. In addition, when interpreting the results of this study, it should be recognized that anemia and mineral metabolism management may be influenced by levels of dialysis adequacy or missed dialysis treatments which have not been accounted for here. However, an analysis of single-pooled Kt/V did not indicate differential trends by race during the study period (Table 1). Finally, this study did not consider the potential for

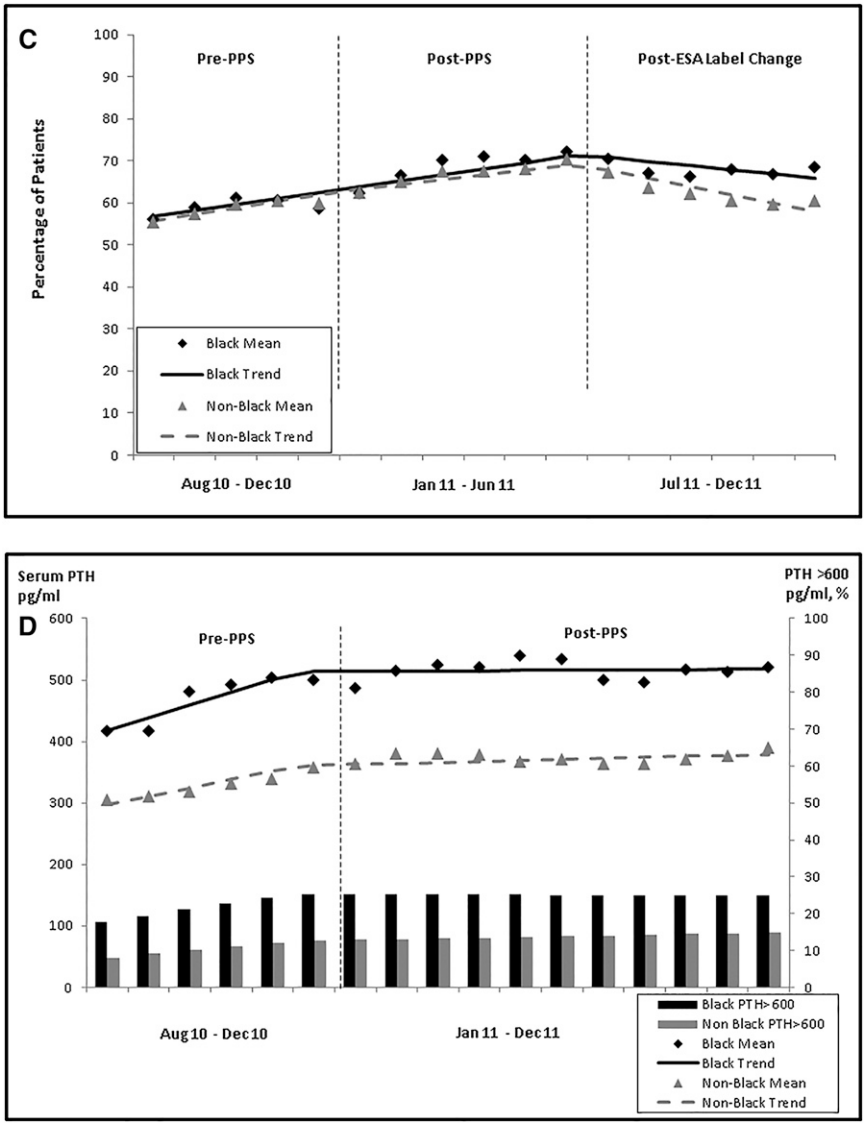

Figure 1. Continued. (C) Similar initial increases in IV iron use over time for black and non-black patients not sustained in post-ESA label change period. (D) Increasing and then stabilizing serum PTH for black and non-black patients.

differences by race in other aspects of ESRD care or in primary outcomes such as mortality, hospitalization, dialysis modality, and quality of life, which should be part of an overall assessment of the impact of the bundled payment system. Because more time may be needed to fully adopt certain practice changes, it may be more appropriate to examine these types of outcomes when longer-term follow-up data are available.

To our knowledge, this is the first study explicitly examining the impact of the recent ESRD payment reform on racial disparities in care. Our findings are based on several key indicators of clinical practices and laboratory measures related to anemia and mineral metabolism, and this national sample is likely to be reflective of care received by United States dialysis patients during the first full year of the bundled payment system. While the adoption of prospective payment systems across health care settings can be used to promote greater efficiency and potentially lead to certain improvements in quality of care, they may pose risks related to access or quality of care for certain populations whose higher costs are not accounted for by methods for case-mix adjustment. The current study suggests this was not occurring in the context of dialysis facility management of anemia and mineral metabolism among United States dialysis patients, based on the initial experience under the new bundled payment system.

CONCISE METHODS

Data Source

Medication use and laboratory measures were assessed using data from the DPM. The DPM was developed as a United States–specific initiative within the DOPPS to monitor trends in dialysis practice during and after implementation of the ESRD PPS using a stratified random sample of 120–140 hemodialysis facilities in the United States, with monthly data summaries reported since August 2010. This national facility sample includes an oversampling of rural and small-chain/independent facilities, and weights are used to recover nationally representative estimates. The DPM sampling plan and study methods have been described previously and are available on the study website (http://www.dopps.org/dpm).[8,28,29]

The present analysis examines monthly cross-sectional data from August 2010 through December 2011. Anemia management measures in this analysis included Hgb (g/dl), ESA use (epoetin alfa or darbepoetin alfa, IV or subcutaneous administration), IV epoetin alfa dose (EPO; U/wk), IV iron use and dose (mg/mo), serum ferritin (ng/ml) levels, and transferrin saturation. Mineral metabolism management measures in this analysis included PTH (pg/ml), IV vitamin D use and dose (μg/wk), cinacalcet use, and phosphate binder use. The total number of facilities included in this analysis was 132. The total number of unique (period-prevalent) patients in this analysis was 7384. Patient counts each month (point-prevalent) ranged from 3753 to 4528, with a mean of 4202 patients/mo.

Statistical Analyses

All analyses used sampling weights and estimation procedures that account for the multistage probability sampling design. Because of the modular data collection procedures, separate weights were estimated for outcomes related to medication use and laboratory test results,

accounting for any differential nonresponse based on five "census" variables: age, years on dialysis, sex, race, and diabetes as primary cause of ESRD. Baseline characteristics were summarized for blacks and nonblacks using means and SEMs for continuous variables and proportions for categorical variables. Differences between groups were assessed using *t* tests for continuous variables and the Rao-Scott chi-squared test for categorical variables, which adjusts for survey design.

To examine anemia outcomes and related treatments, we created three time categories: (*1*) August 2010–December 2010 ("Pre-PPS" period); (*2*) January 2011–June 2011 ("Pre-ESA label change" period); and (*3*) July 2011–December 2011 ("Post-ESA label change" period). As the ESA label change was not expected to substantially affect mineral metabolism measures and related treatments, these variables were analyzed during only two time periods: (*1*) August 2010–December 2010 ("Pre-PPS" period) and (*2*) January 2011–December 2011 ("Post-PPS" period).

Monthly cross-sectional means and proportions were examined for anemia-related measures at four key time points: August 2010, January 2011, June 2011, and December 2011. This was repeated for mineral metabolism measures, excluding June 2011. Measures of medication use and laboratory test results were available for 80%–90% of the study sample at each time point. Delivered injectable iron and vitamin D doses were available only from facilities affiliated with an LDO. Estimated means were tested for differences by race from the August 2010 baseline. Summary measures for all months were presented graphically and overlaid with model-based results.

Linear splines were used in survey-weighted linear and logistic regressions to estimate trends over time. For anemia measures, spline knots were placed at January 1, 2011, and June 24, 2011, to correspond with implementation of the PPS and the ESA label change, respectively. For mineral metabolism measures, a single knot at January 1, 2011, was used. Race-specific trends were estimated for black and nonblack patients in a single model using product terms, and estimates were scaled to reflect a 30-day change. The multivariate Wald statistic was used to test whether the trends for each outcome differed according to race (*i.e.*, whether the race-by-time slope interaction terms were simultaneously equal to zero). All models were adjusted for age (continuous), sex, predialysis weight (continuous), years since dialysis initiation, ESRD cause, and the United States geographic region where the dialysis facility was located (categorized as North, South, East, or West). In separate analyses, we further adjusted the models by patient ethnicity, insurance coverage, dialysis organization type, and facility location in urban or rural setting.

All analyses and data manipulations were performed using SAS software, version 9.2 (SAS Institute Inc., Cary, NC).

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DISCLOSURES

None.

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