Trends in Anemia Management in US Patients on Dialysis, 2005-2011

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Introduction

- The landscape of anemia management practice changed with clinical trials in the 2000s that showed increased risk of adverse events when erythropoiesis stimulating agents were used to target higher hemoglobin (Hb) levels. In 2011, the ESA label was revised and a new capitated payment system for dialysis reimbursement was implemented.
- We investigated the impact of these regulatory events on anemia management in dialysis patients.

Methods

- Data source: Centers for Medicare & Medicaid (CMS) end-stage renal disease (ESRD) database, including:
 - Medical Evidence Report (form CMS-2728).
 - Death Notification (form CMS-2746).
 - Medicare Part A (inpatient, outpatient, skilled nursing facility, home health, hospice) claims.
 - Medicare Part B (physician/supplier) claims.
- We created annual cohorts composed of prevalent and incident patients receiving peritoneal dialysis (PD) or in-center hemodialysis (HD) between January 1, 2005, and December 31, 2011. Included patients;
 - · Were aged at least 18 years.
 - Had at least 9 months on dialysis.
 - Had at least 6 months with Medicare (Parts A and B) as primary payer.
- Hemoglobin levels and ESA and IV iron use and dose were derived from outpatient dialysis claims. As almost all patients on dialysis receive epoetin alfa (EPO), patients receiving other ESAs were excluded.
- Monthly EPO and iron doses were calculated for months with at least 7 outpatient days; months with no use were assigned zero
- Hb levels and EPO and IV iron use and dose were summarized quarterly by modality.
- Quarterly EPO and iron use (Y/N) were defined as any use in the quarter.

Results

- Between 2005-2011 the mean age remained constant, the percentage of men and that of diabetes as primary cause of ESRD increased, and mean BMI increased. The percentage of patients reporting white race decreased and those reporting other (non-white, non-black) race increased (Table 1).
- Among HD patients, from 2005 to 2011:
 - EPO use decreased from 92% to 85%; iron use increased from 69% to 75% (Figure 1).
- Mean monthly ESA dose fell from 69,000 to 43,000 units/month (Figure 2).
- Mean quarterly iron dose rose from 539 mg in the first quarter of 2005 to 647 mg in the second quarter of 2011, then fell to 516 mg in the last quarter of 2011 (Figure 2).
- Hb levels fell from 11.9 g/dL to 10.7 g/dL (Figure 3).
- Among PD patients, from 2005 to 2011:
 - EPO use remained constant at about 70%; iron use rose from 21% in 2005 to 39% in 2011 (Figure 1).
- Mean monthly EPO dose was stable between 2005 and 2009, but began to decline in 2010, falling from 43,000 units at the beginning of 2010 to 28,000 units by the end 2011 (Figure 2).
- Quarterly iron dose, in contrast, rose from 90 mg the first quarter of 2005 to 165 mg in the third quarter of 2011. The dose was slightly lower in the last quarter of 2011, 145 mg (Figure 2).
- Hb levels fell from 11.6 g/dL in 2005 to 10.5 g/dL by the end of 2011 (Figure 3).

Table 1.
Patient
characteristics
over the years

	2005	2006	2007	2008	2009	2010	2011
Number of patients	252,276	254,570	259,316	264,006	269,873	278,713	292,083
Mean age (years)	62.2	62.2	62.2	62.2	62.2	62.2	62.3
Sex (% male)	54.1	54.4	54.6	54.9	55.1	55.2	55.3
Race (%)							
White	43.5	42.8	42.5	42.1	41.7	41.2	40.9
Black	37.9	38.3	38.3	38.3	38.2	38.4	38.5
Other	18.6	18.8	19.1	19.6	20.0	20.3	20.6
ESRD cause (%)							
Diabetes	42.9	43.2	43.5	43.7	43.9	44.1	44.2
Hypertension	29.2	29.2	29.0	29.0	29.0	29.1	29.3
GN	11.7	11.3	10.9	10.6	10.4	10.1	9.8
Other	16.2	16.3	16.5	16.7	16.7	16.7	16.7
Mean BMI (kg/m²)	28.0	28.3	28.6	28.8	29.1	29.3	29.5



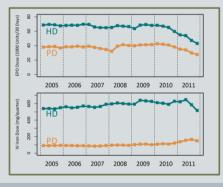


Figure 1. EPO and IV iron use by modality, 2005-2011

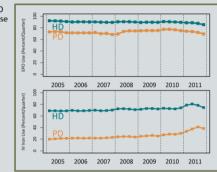
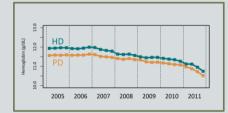


Figure 3. Hb levels (among EPO users) by modality, 2005-2011



Conclusions

- Treatment with EPO has been shifting downward and contributed to decreasing Hb concentrations in both the HD and PD populations.
- Early evidence from multiple data systems including USRDS have shown an increase in the use of red blood cell transfusion during this same period, but information on any changes in the cardiovascular risks have not been rigorously explored.
- Future studies should investigate whether recent changes in EPO utilization have changed the benefit:risk profile of anemia treatment.



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