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 sources: 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).
  - Medicare Part B (physician/supplier).

- 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:
  - 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 ESA 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 men and those of diabetes as primary cause of ESRD increased, and mean BMI increased. The percentage of patients reporting white, non-black race decreased and those reporting other (non-white, non-black) race increased (Figure 1).
- Among HD patients, from 2005 to 2011:
  - EPO use decreased from 9% to 85%; iron use increased from 6% to 75% (Figure 1).
  - Mean monthly ESA dose fell from 69,000 to 43,000 units at the beginning of 2005 to 24,000 units in the second quarter of 2011 (Figure 2).
- 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 3). Table 1.

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.