

Introduction

Physician practice patterns of anemia management in patients within the United States (US) receiving hemodialysis (HD) have changed, as recently noted in the prevalent end-stage renal disease (ESRD) population,¹ as a result of significant changes to the erythropoiesis-stimulating agent (ESA) labels and new prospective clinical trials (Figure 1). In June 2011 the Food and Drug Administration (FDA) revised ESA labels, changing the target hemoglobin (Hb) levels and recommending more conservative ESA dosing for both pre-ESRD and ESRD patients.² While the effects of these changes in ESRD patients are tracked systematically, the same is not true for pre-ESRD patients. To date, there has not been a large scale assessment of the change in anemia management in pre-ESRD. In order to do so, this analysis sought to use the first hemoglobin on dialysis as a surrogate for the status of pre-ESRD anemia care in the US.

Objective

We sought to describe the mean and distributional changes in Hb among incident ESRD patients related to the contemporary changes.

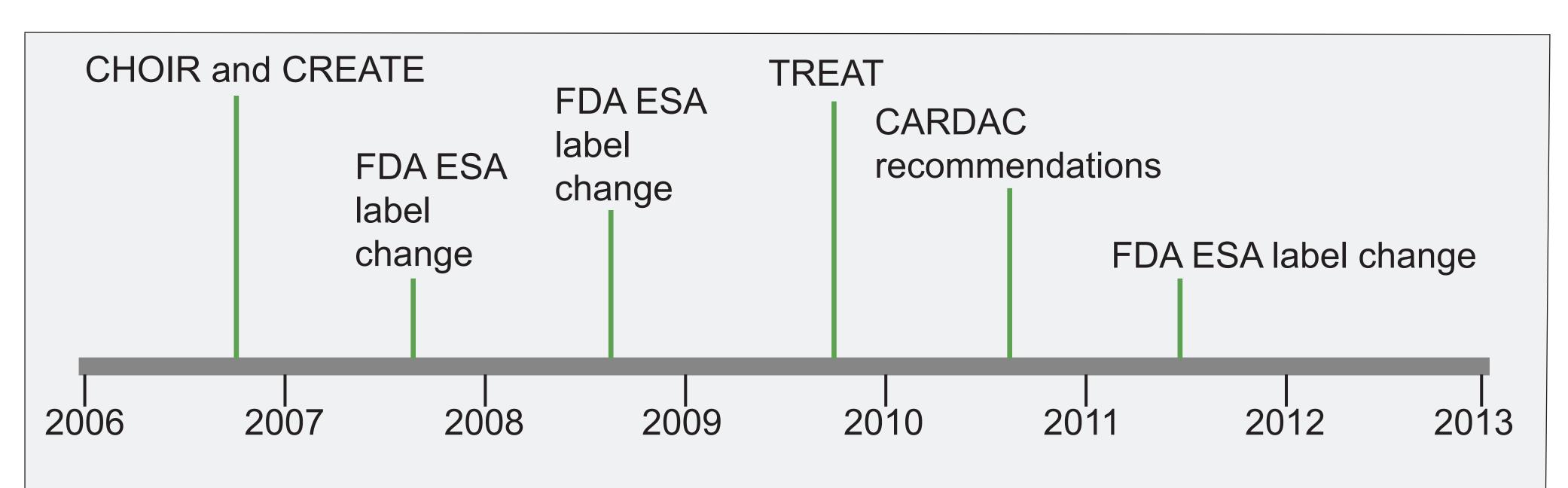


Figure 1. Timeline of Key Events Influencing Anemia Management

Methods

- We conducted a retrospective analysis of incident patients at a large dialysis organization.
- Incident patients were defined as patients beginning dialysis for the first time and having received HD for < 90 days from 1 January 2008 – 31 March 2012 (Table 1).
- We have excluded patients transferring from other dialysis facilities from the analysis, thus only incident patients are included.
- The concentration of Hb at first measurement in each incident dialysis patient was used as a surrogate for pre-ESRD anemia management. Mean values for the first Hb test after starting dialysis (incident patients) were used.
- Population mean and percent of patients with Hb < 10 g/dL were plotted over time.

Hemoglobin Trends in Incident End-Stage Renal Disease Patients from 2008-2011 Scott Sibbel, PhD¹ and Joe Weldon, MBA;¹ Rhoda Silva Brown;¹ Allen Nissenson, MD, FASN;² Mahesh Krishnan, MD, MBA, MPH, FASN¹

¹DaVita Clinical Research, Minneapolis, MN; ²DaVita Inc., Denver, CO

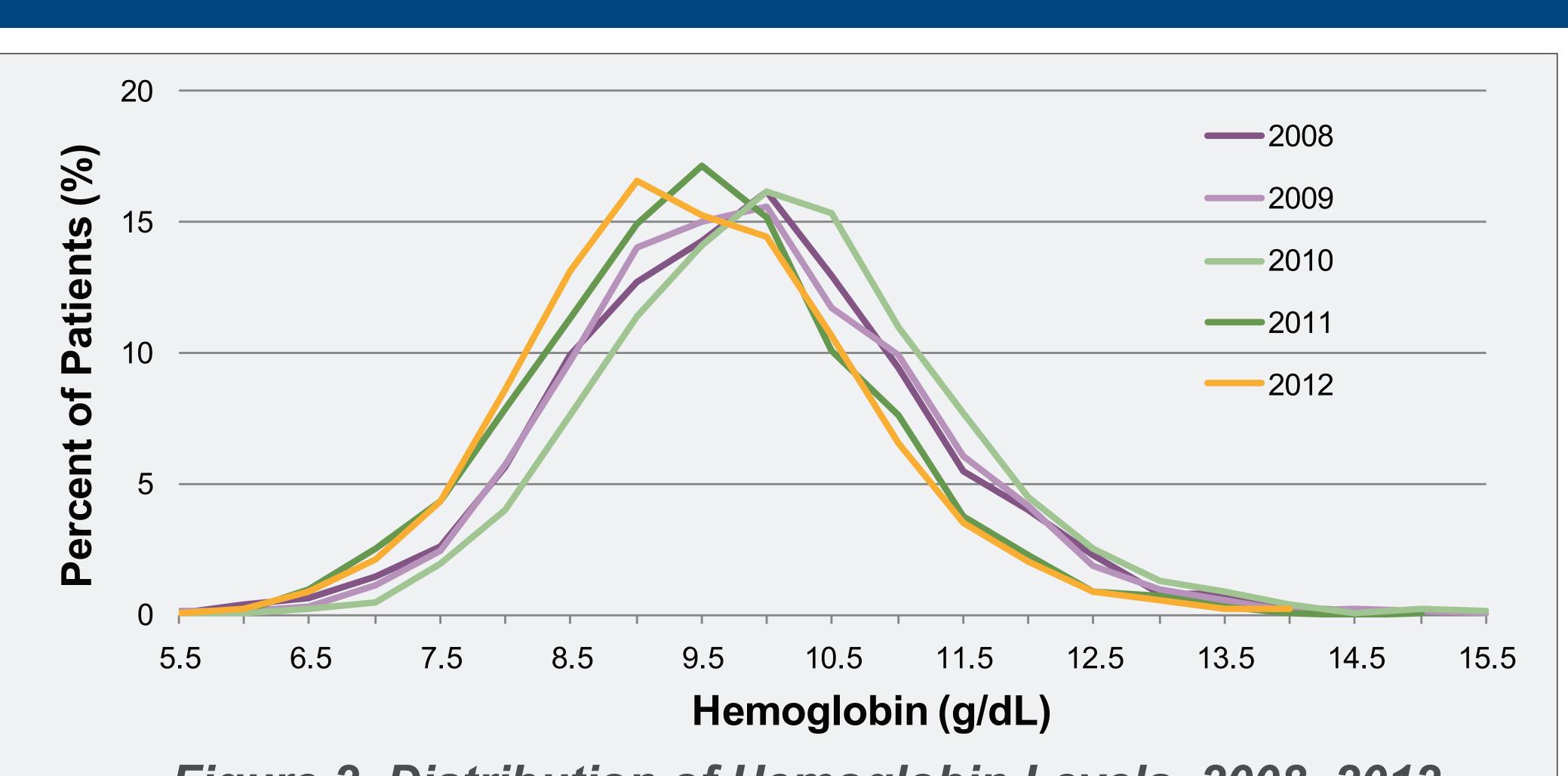
Results

- The distribution of mean Hb concentration at dialysis initiation shifted, moving from a mode of 10.5 g/dL in January 2008 to a mode of 9.5 g/dL in January 2012 (Figure 2).
- The proportion of patients with Hb < 10 g/dL showed a concurrent increase (42.0%–56.6%; Figures 3 and 4).
- A total of 116,801 incident patients were included in the analysis (Figure 4).
- Mean Hb concentrations at the first test after starting dialysis demonstrated a modest decline over the 4 years, shifting from 10.3 ± 1.4 g/dL (mean \pm SD) to 9.9 ± 1.2 g/dL between January 2008 and January 2012 (Table 1; Figure 4).
- Initial Hb levels appeared to plateau after June 2009, and a slight decline was observed after the FDA label change in late June 2011 (Figure 4).

	January 2008	January 2009	January 2010	January 2011	January 2012
Ν	2,343	2,447	2,286	2,447	2,648
Hemoglobin (mg/dL) ^a	10.3 ± 1.4	10.4 ± 1.3	10.0 ± 1.3	10.1 ± 1.3	9.9 ± 1.2
Age (yrs) ^a	61.0 ± 15.7	61.8 ± 15.8	62.1 ± 15.7	62.1 ± 15.3	62.4 ± 15.5
Female (%)	42.3	43.8	41.3	40.7	43.2
Race/Ethnicity(%)					
Native American/Alaskan	1.4	1.3	0.8	1.2	1.2
Asian	4.0	4.5	3.9	4.3	4.5
African American	29.3	30.0	29.7	29.6	27.3
Hispanic	14.2	14.1	14.7	14.4	15.3
Other/Unknown	0.1	0.0	0.1	0.1	0.2
Primary Cause of ESRD(%)					
Diabetic Kidney Disease	46.7	48.5	45.8	44.5	46.3
Hypertension Kidney Disease	e 29.8	28.6	30.5	29.6	28.2
Polycystic Kidney Disease	2.1	1.7	1.4	1.2	1.5
Other/Unknown	19.6	19.2	19.7	21.7	18.9
Vascular Access (%)					
Arteriovenous Fistula	13.5	14.5	15.9	14.1	15.9
Arteriovenous Graft	3.9	3.6	3.2	3.1	2.8
Central Venous Catheter	76.1	77.9	75.1	75.8	73.8

Table 1. Patient Demographics

Mean ± standard deviation is shown





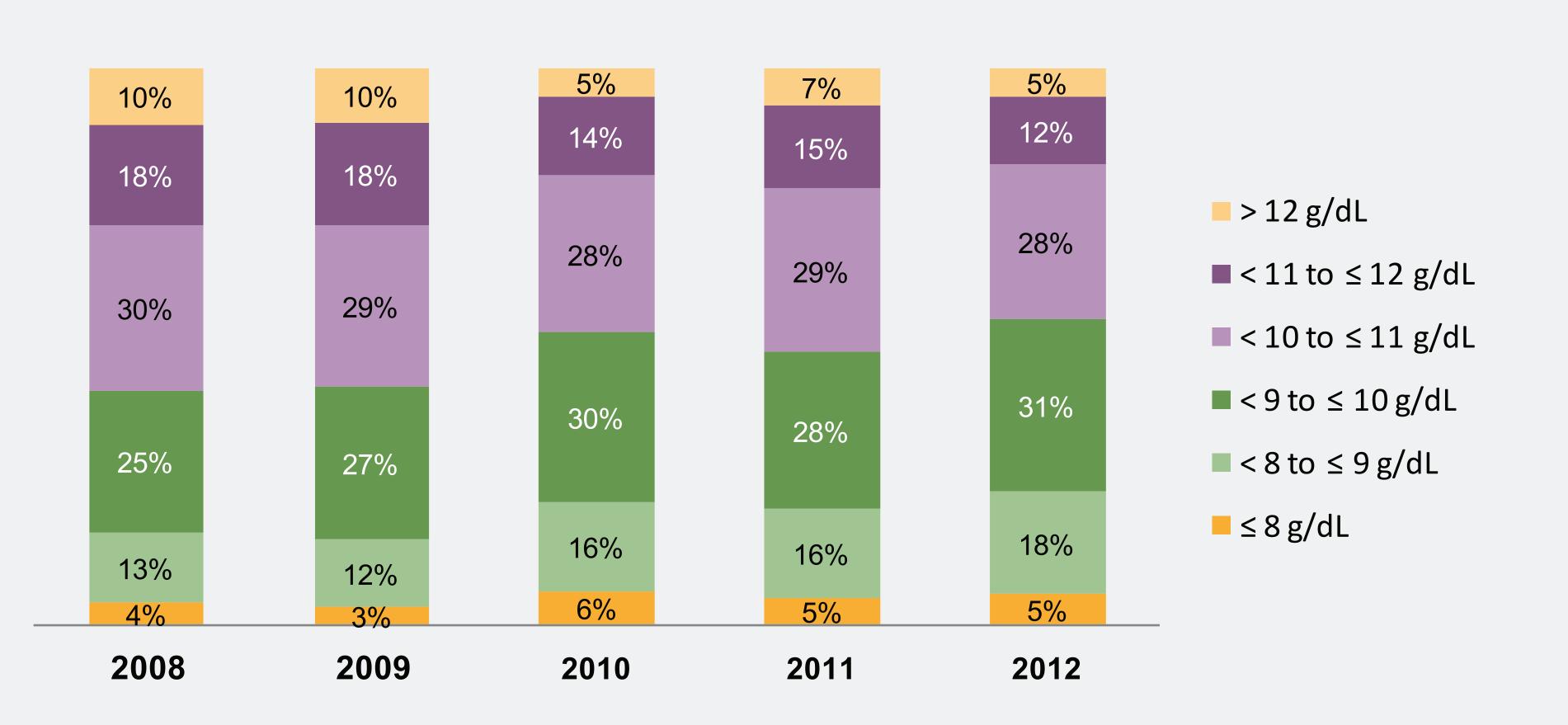
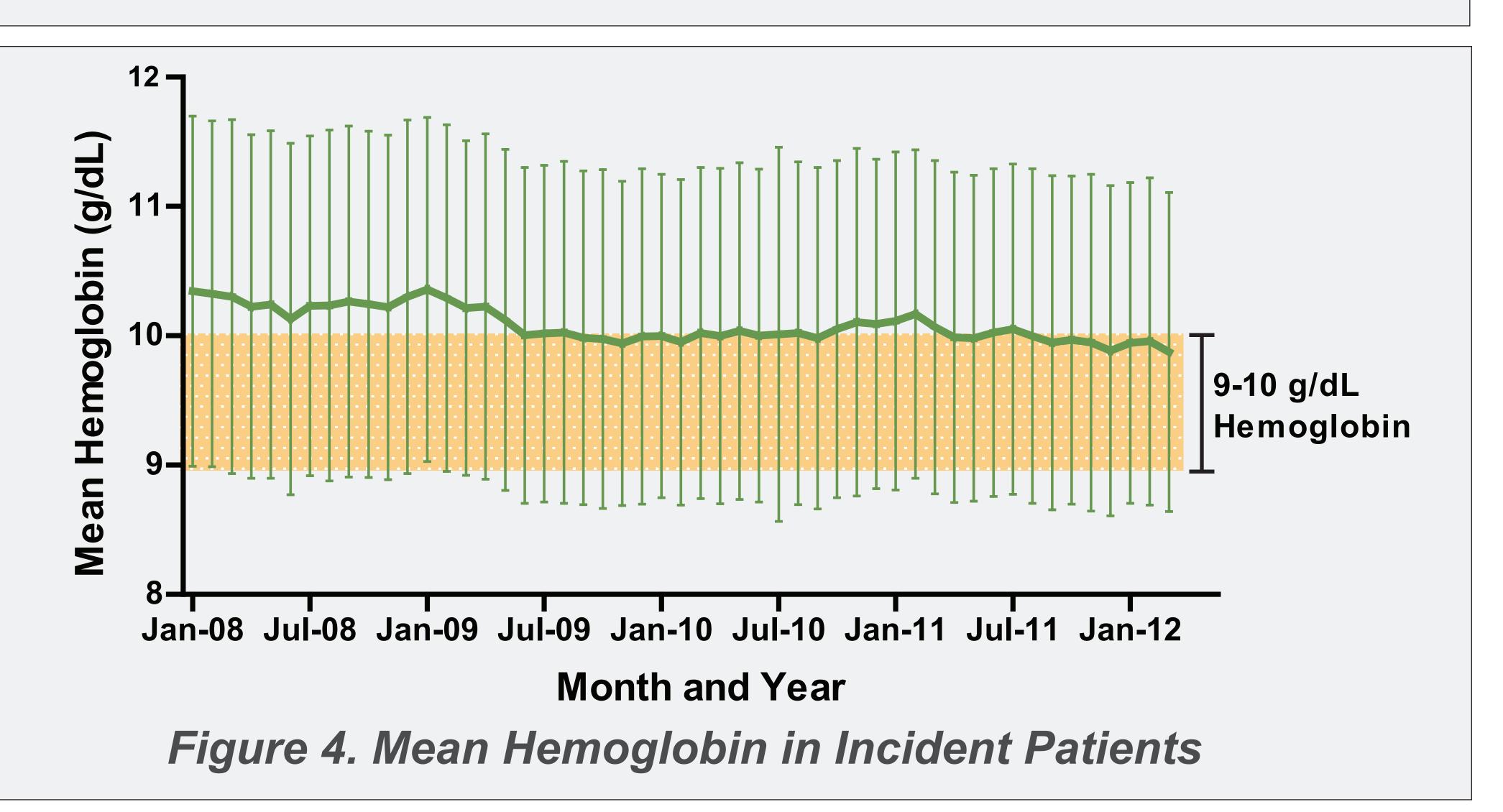


Figure 3. Hemoglobin Distribution by Category



Summary

- From January 2008 to March 2012, the proportion of patients beginning dialysis with a Hb of < 10 g/dL increased and incident patient mean Hb concentrations decreased.
 - -These data result from a reduction in the Hb mean and mode, data do not result from an increased or change in the variability of the Hb distribution.
- In July 2011, over 50% of patients began dialysis with Hb levels < 10 g/dL.
- We observed modest steady reductions in Hb levels that temporally correspond to revised FDA guidelines and label changes for ESAs in the same time period.

Conclusions

- Patients started dialysis with lower initial Hb concentrations, reflecting more conservative predialysis chronic kidney disease care by the nephrology community.
- These changes were temporally aligned with the changing guidance for the use of ESAs in the predialysis setting by the FDA.
- The proportion of patients beginning dialysis with lower Hb (Hb < 10 g/dL) increased and the mean hemoglobin fell, which have resulted in more patients in need of a more intense focus on anemia management to ensure the continued best clinical outcomes.

References

- Collins AJ. End-stage renal disease payment policy changes: The new "bundled" dialysis prospective payment system in the United States. 2012. Changes in epoetin and IV iron use occcuring in 2011. Available at: http://www.usrds.org/2012/pres/USDialysisBundle_impact_NKFCM2012.pdf. Accessed 18 June 2012.
- FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease. 2011 http://www.fda.gov/drugs/drugsafety/ucm259639.htm. Accessed 5 October 2012.

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*Correspondence: scott.sibbel@davita.com or joe.weldon@davita.com

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