Chapter 2:
Clinical Indicators and Preventive Care

Anemia

- In May 2016, the majority (64.7%) of hemodialysis (HD) patients had hemoglobin (Hgb) levels from 10 to <12 g/dL, while 13.6% had Hgb ≥12 g/dL, 14.9% had Hgb from 9 to <10 g/dL, and 6.8% had Hgb <9 g/dL. The mean Hgb was 10.8 g/dL (Figure 2.1.b).
- In May 2016, the majority (56.2%) of peritoneal dialysis (PD) patients had Hgb levels from 10 to <12 g/dL, while 20.3% had Hgb ≥12 g/dL, 16.0% had Hgb from 9 to <10 g/dL, and 7.5% had Hgb <9 g/dL. The mean Hgb was 10.9 g/dL (Figure 2.1.b).
- As of 2015, three different erythropoiesis-stimulating agents (ESAs) were prescribed to dialysis patients in the United States (U.S.). December 2015 claims data indicated monthly use rates among HD patients on dialysis ≥90 days of 42.6% for epoetin (EPO) alfa, 14.0% for darbepoetin, 20.5% for pegylated EPO (PEG-EPO) beta; 19.7% of these patients were not using an ESA. Among PD patients, 40.4% were using EPO alfa, 9.2% darbepoetin, 9.2% PEG-EPO, and 38.7% were not using an ESA (Figures 2.2.d and 2.8.d.).
- For U.S. HD patients in 2014 to 2015, little change was seen in the monthly percent intravenous (IV) iron use (61.2% to 60.0%) and mean monthly IV iron dose (295.6 mg to 294.0 mg; Figure 2.4). For PD patients little change was also seen in monthly percent IV iron use (24.7% to 25.3%) or mean monthly IV iron dose (195.5 mg to 196.2 mg; Figure 2.10).
- Serum ferritin levels increased slightly in all dialysis patients from 2014 to 2016. As of May 2016, 31.6% of HD patients had serum ferritin of 801-1200 and 21.9% had >1200 ng/mL. Among PD patients, 22.8% had serum ferritin of 801-1200 and 14.7% had >1200 ng/mL (Figures 2.6 and 2.12).

Serum Albumin

- In May 2016, 17.7% of HD and 42.8% of PD patients were hypoalbuminemic (<3.5 g/dl).

Mineral and Bone Disorders

- In May 2016, 59.5% of HD and 56.9% of PD patients had serum calcium levels within the range of 8.4-9.5 mg/dL. About 2% of patients receiving either dialysis modality had serum calcium levels greater than 10.2 mg/dL; 18.1% of HD patients and 23.9% of PD patients had calcium levels less than 8.4 mg/dL (Figures 2.14 and 2.15).
- In May 2016, 65.9% of HD patients and 70.1% of PD patients had serum phosphorus levels greater than 4.5 mg/dL (Figures 2.16 and 2.17).

Preventive Care

- In 2015, 86.5% of diabetic end-stage renal disease (ESRD) patients received at least one glycosylated hemoglobin (HbA1c) test, 71.8% a lipid test, and 46.9% a dilated eye exam. However, only 34.0% of diabetic ESRD patients received comprehensive diabetes monitoring that includes at least one of each of these tests. This was a decline from 36.4% comprehensive monitoring in 2010 (Figure 2.18).
- In the 2014-2015 flu season 72.2% of patients received an influenza vaccination. Although this rate had been stable over the last two years and the percent vaccinated has increased from 56.7% a decade earlier, the rate of flu vaccination was still below the Healthy People 2020 (HP2020) target of 90% (Figure 2.19.a).

Introduction

Given the high morbidity and mortality of individuals with ESRD who are receiving dialysis, initiatives aimed at quality improvement of renal replacement therapies (RRT) have long been a priority. Notable efforts from the Centers for Medicare & Medicaid Services (CMS) include assessment and reporting of provider performance through Dialysis Facility Reports (DFR) and Dialysis Facility Compare (DFC), as well as the Quality Incentive Program (QIP), which ties Medicare reimbursement to achievement of selected quality targets. Data collection for these projects has undergone a transition from paper-based data entry to web-based or electronic data entry using the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). Implemented nationally in May 2012, this system allows facilities to submit monthly laboratory and clinical data for patients under their care. The system is still evolving, however, and data are select and not yet fully captured.

Methods

The findings presented in this chapter were drawn from data sources from the Centers for Medicare & Medicaid Services (CMS). Details of these are described in the *Data Sources* section of the *ESRD Analytical Methods* chapter.

See the *Analytical Methods Used in the ESRD Volume* section of the *ESRD Analytical Methods* chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for these figures and tables are available on the USRDS website.

Clinical Indicators

In Figure 2.1, we present CROWNWeb data from May 2016 for a selection of clinical indicators relating to dialysis adequacy, achieved Hgb level, hypercalcemia, and serum albumin. Figure 2.1.a shows that achievement of dialysis adequacy targets for HD was nearly universal, with 96.7% of patients achieving a single pool Kt/V ≥1.2 (for more information about Kt/V see the Glossary). Achievement of the dialysis adequacy target for PD, a weekly Kt/V ≥1.7, was somewhat lower, at 88.9% (Figure 2.1.a).

Views on anemia treatment with ESAs have evolved in recent years, as safety concerns have emerged from controlled CKD clinical trials; study participants experienced greater risks of death, serious adverse cardiovascular reactions, and stroke when administered ESAs to achieve hemoglobin levels of greater than 11 g/dL. The results of these trials led the FDA, in 2011, to recommend reducing or interrupting the dose of ESA when a patient's hemoglobin level approached or exceeded 11 g/dL. Current guidelines do not specify an appropriate lower limit, however, resulting in generally lower Hgb levels among dialysis patients.

CROWNWeb includes data from both Medicare and non-Medicare insured patients, and thus presents a more representative view of Hgb levels for the dialysis population than was previously possible through analyses based only upon claims data (Figure 2.1.b). In May 2016 the majority (64.7%) of both ESA-treated and non-treated HD patients had Hgb levels in the range of 10 to 12 g/dL, with 13.6% having Hgb ≥12 g/dL. The pattern was similar with PD patients, though a somewhat higher percentage (20.3%) had Hgb ≥12 g/dL. Later in this chapter, we utilize Medicare claims through 2015 in anemia trend analyses, and CROWNWeb data to describe the iron indices of ferritin and transferrin saturation (TSAT).

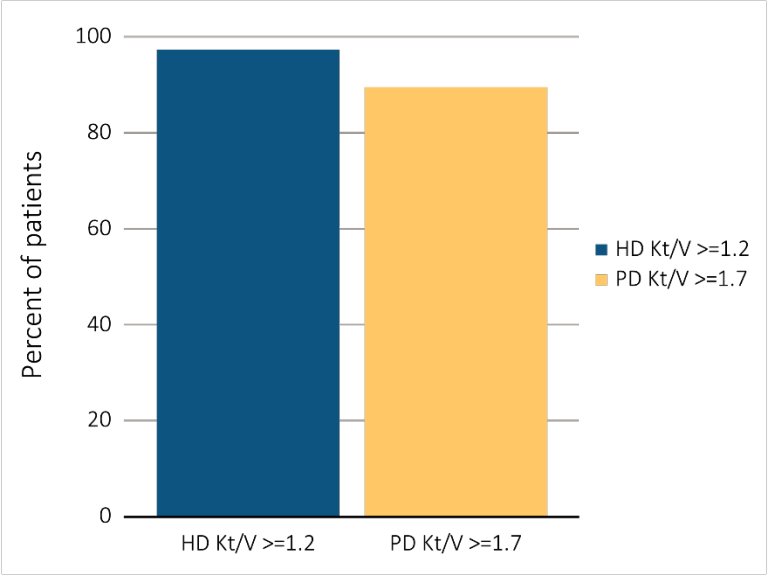
In Figure 2.1.c we present CROWNWeb data as of May 2016 on the percentage of dialysis patients having serum calcium levels >10.2 mg/dL. This was calculated as a three-month rolling average, similar to the methods utilized by the CMS ESRD Quality Incentive Program (QIP). The rationale for this quality measure is to encourage avoidance of hypercalcemia given its associations with vascular calcifications and cardiovascular events. For both modalities, the percent of patients with hypercalcemia has declined compared to May 2015. Later in the chapter, we present additional CROWNWeb data on trends in serum calcium and phosphorus levels.

Figure 2.1.d presents CROWNWeb data as of May 2016 on the distribution of serum albumin levels among dialysis patients. Although serum albumin has received much consideration as a potential quality measure and nutritional marker, several concerns

remain. These include its inconclusive link to nutritional status, as other factors, such as chronic inflammation or ongoing urinary protein loss can also lower serum albumin. In addition, it is unclear whether nutritional or other interventions can improve serum albumin levels. Nevertheless, given its importance as a prognostic marker and a strong association with mortality, we include national information on albumin levels. As of May 2016, 17.7% of HD and 42.8% of PD patients were hypoalbuminemic (<3.5 g/dl). The lower levels of serum albumin in PD patients compared to HD patients are thought to be in part due to peritoneal losses of protein.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis versus peritoneal dialysis patients in CROWNWeb data, May 2016: (a) percentage of patients meeting clinical care guidelines for dialysis adequacy; (b) percent distribution of Hgb levels; (c) percentage of patients with serum calcium >10.2 mg/dL; (d) percent distribution of serum albumin levels.

(a) Percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy, by modality



(b) Percent distribution of Hgb levels among prevalent hemodialysis and peritoneal dialysis patients

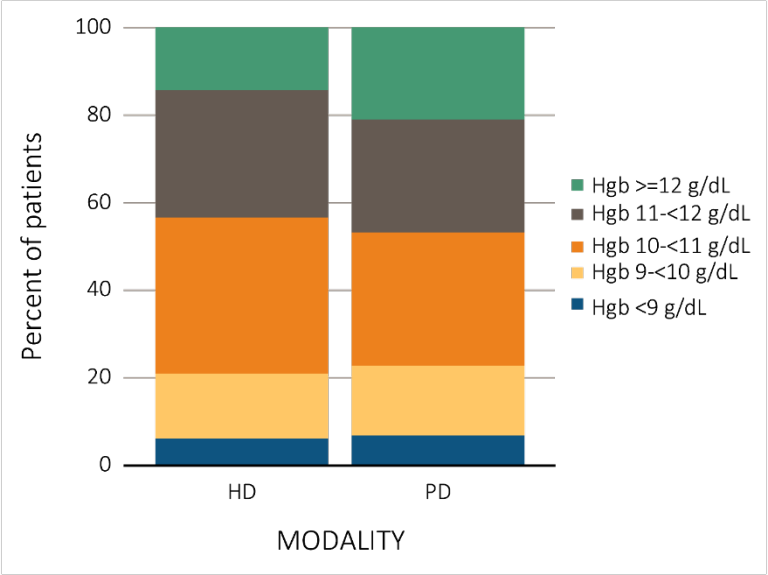
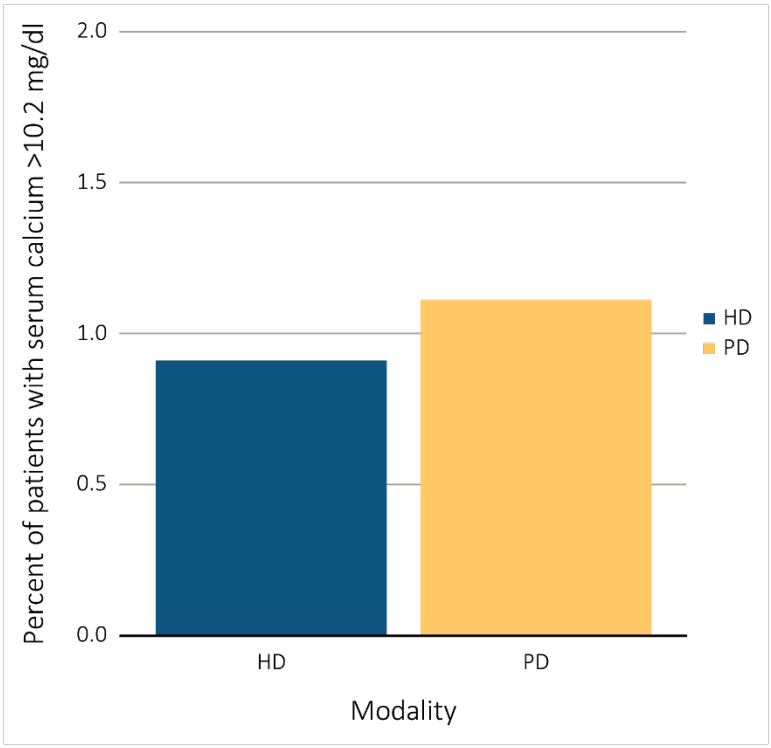


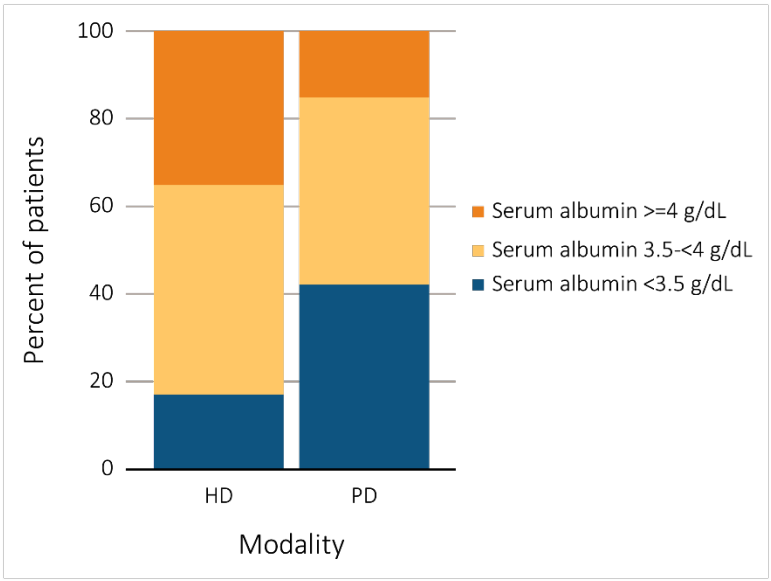
Figure 2.1 continued on next page.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis versus peritoneal dialysis patients in CROWNWeb data, May 2016: (a) percentage of patients meeting clinical care guidelines for dialysis adequacy; (b) percent distribution of Hgb levels; (c) percentage of patients with serum calcium >10.2 mg/dL; (d) percent distribution of serum albumin levels *(continued)*

(c) Percentage of dialysis patients with serum calcium >10.2 mg/dL, by modality



(d) Percent distribution of serum albumin levels among prevalent hemodialysis and peritoneal dialysis patients



Data Source: Special analyses, USRDS ESRD Database. Results shown are for laboratory values reported to CROWNWeb for May 2016, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to May 1, 2016, and who were alive through May 31, 2016; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, who were ≥18 years old as of May 1, 2016, and who were alive through May 31, 2016; (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, who were ≥18 years old as of May 1, 2016, and who were alive through May 31, 2016; and (d) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2016, who were >=18 years old as of May 1, 2016, and who were alive through May 31, 2016. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; HD, hemodialysis; Hgb, hemoglobin; Kt/V, see Glossary; PD, peritoneal dialysis.

Anemia Treatment by Modality

In this section, we describe long-term trends in Hgb levels, ESA use, ESA dose, IV iron use, IV iron dose, levels of iron stores, and red blood cell transfusion rates. We report analyses of CMS claims data by dialysis modality through 2015. Monthly mean IV iron doses are now provided for years 2005 to 2015. Prior to 2012, to meet CMS billing requirements, dialysis providers only reported Hgb values when filing a claim for patients who received an ESA during the given month. Consequently, Hgb values based on CMS claims data prior to 2012 were restricted to ESA-treated patients. Since April 2012, CMS required reporting of Hgb values for all patients, regardless of whether they received an ESA. This allows comparisons of Hgb values for ESA-treated patients to non-ESA treated patients, and to *all* patients.

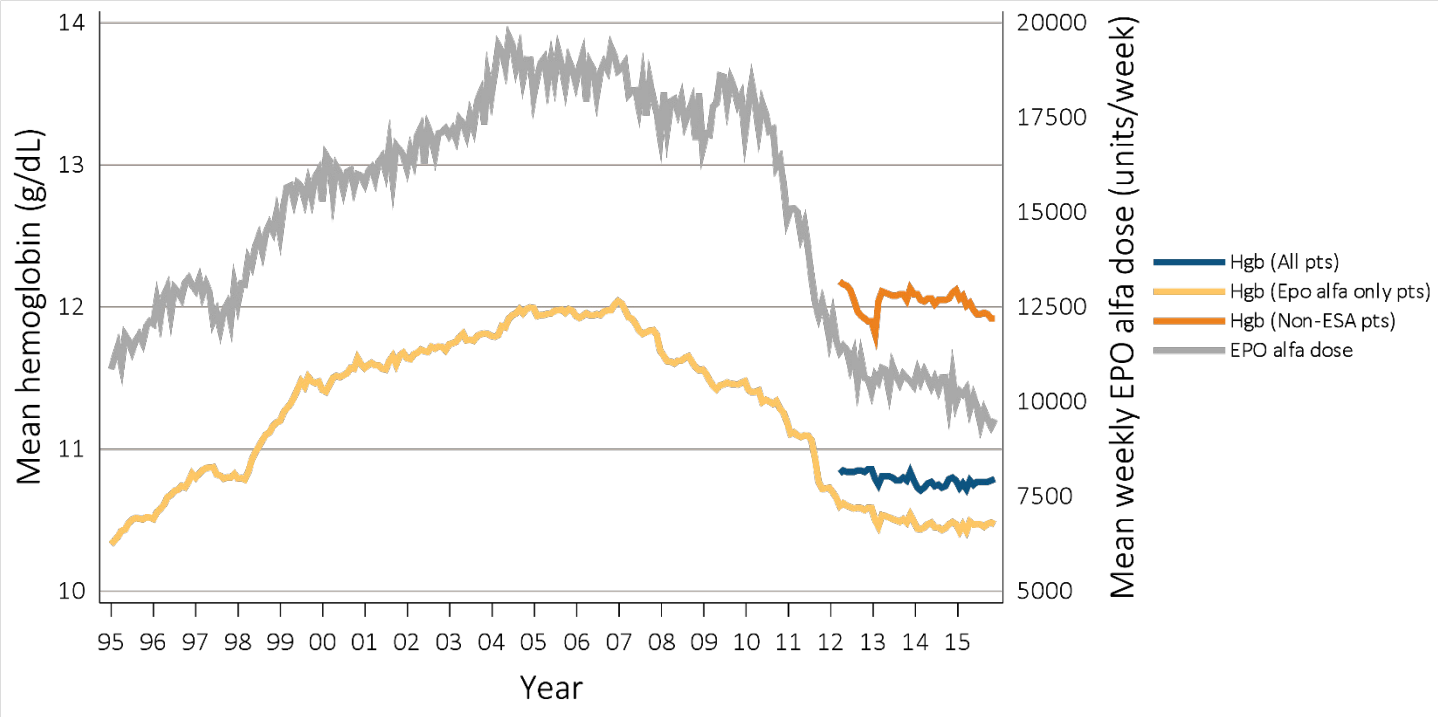
Hgb Levels, ESA Use and Dose in Hemodialysis Patients

CMS data indicate that mean Hgb levels in ESA-treated HD patients have declined substantially since their 2007 peak near 12.0 g/dL (Figure 2.2.a). During 2011, mean Hgb level declined by 0.5 g/dL—from 11.2 g/dL to 10.7 g/dL. Since then, among ESA-treated HD patients on dialysis ≥90 days, Hgb levels have continued to slowly decline to a mean monthly level of 10.5 g/dL in 2015. Mean monthly Hgb values in 2015 were 10.8 g/dL for all HD patients on dialysis ≥90 days and 12.0 g/dL for non-ESA treated patients. Similarly, analyses of CROWNWeb data indicated a mean Hgb level of 10.8 g/dL for all HD patients in May 2015.

In 2015, 80%-83% of HD patients on dialysis for ≥90 days had a claim for ESA use during any single month (Figure 2.2.d). From December 2014 to December 2015, there was a large shift in the type of ESA prescribed to Medicare patients. In December 2014, 77.4% and 5% of patients were prescribed EPO alfa and darbepoetin, but by December 2015, 42.6%, 14.0%, and 20.5% were prescribed EPO alfa, darbepoetin, and PEG-EPO. Between December 2006 and December 2015, mean weekly EPO alfa doses (averaged over a month) declined by nearly 50% in HD patients. The mean weekly EPO alfa dose (averaged monthly) declined slightly from 2014 to 2015. When calculated for the prevalent cross-section of HD patients on dialysis ≥90 days, the mean monthly dose in 2015 (averaged across 12 months) indicated an average weekly EPO alfa dose of 9,849 ± 99.3 units.

vol 2 Figure 2.2 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb level and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PEG-EPO beta dose, and (d) percent ESA use monthly, Medicare claims, 1995-2015

(a) Mean monthly Hgb level and mean weekly epoetin alfa dose



(b) Mean monthly Hgb level and mean monthly darbepoetin dose

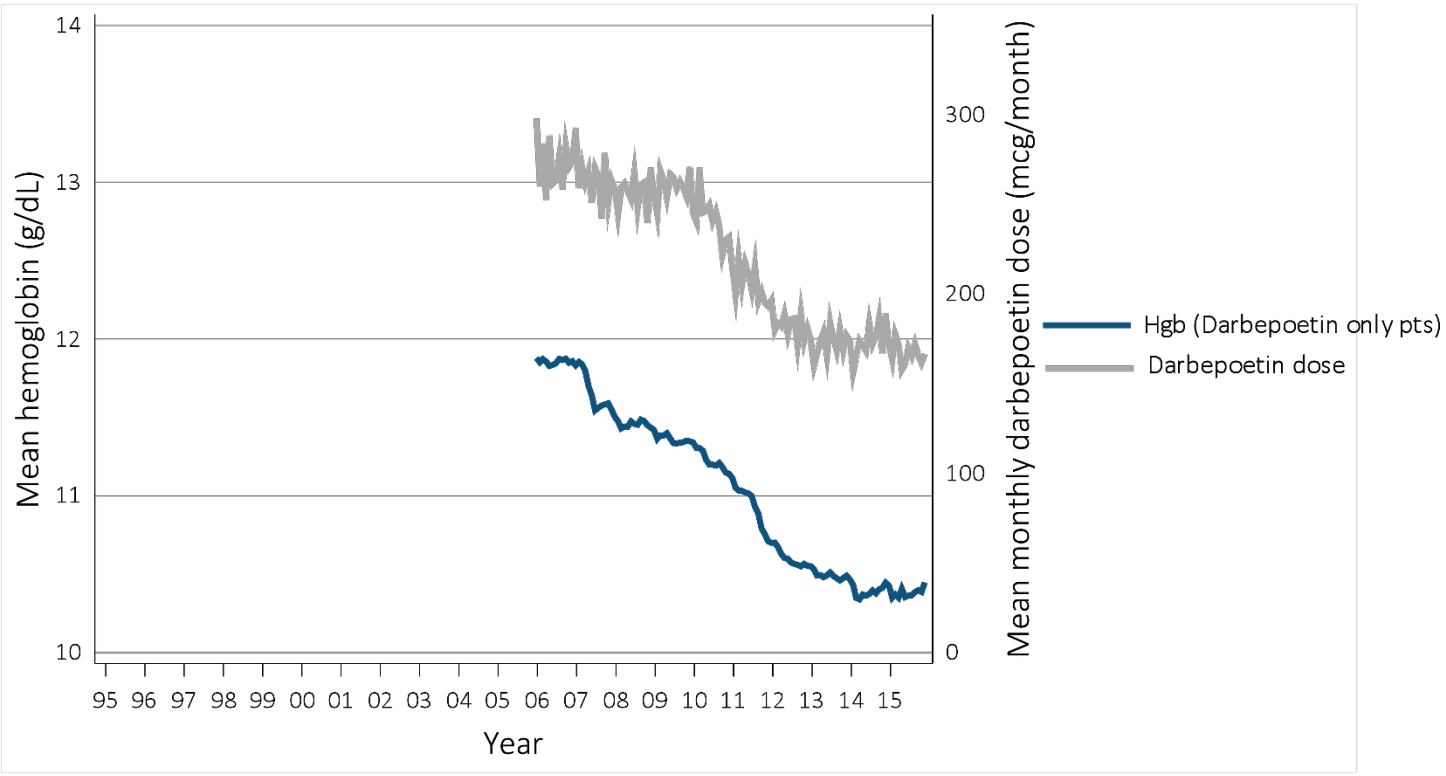
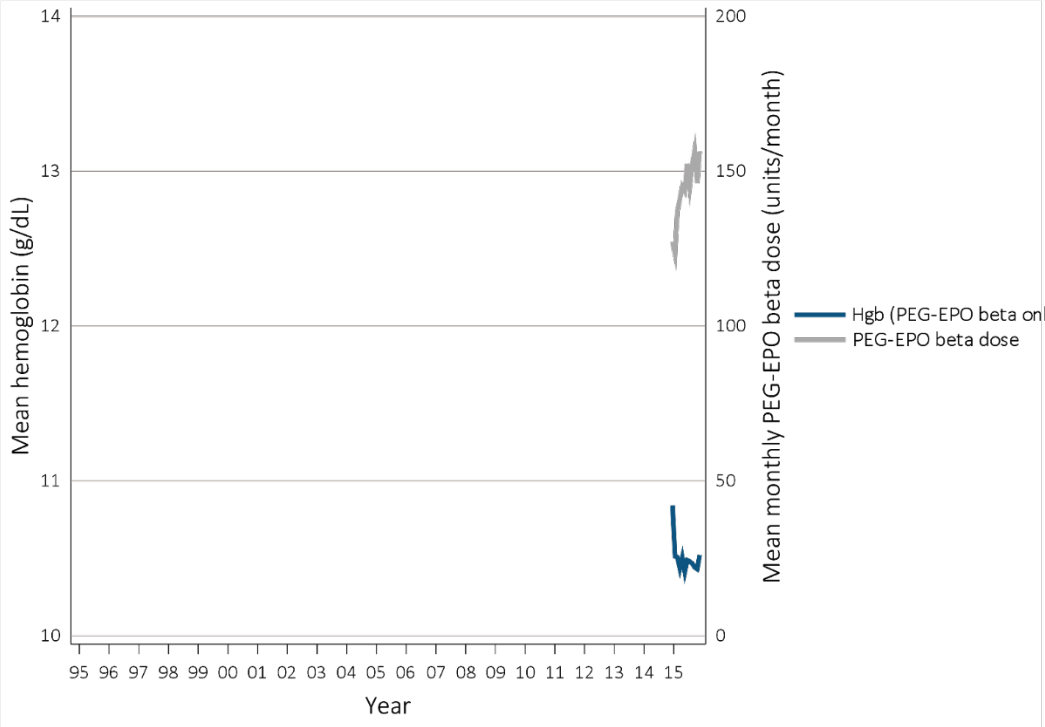


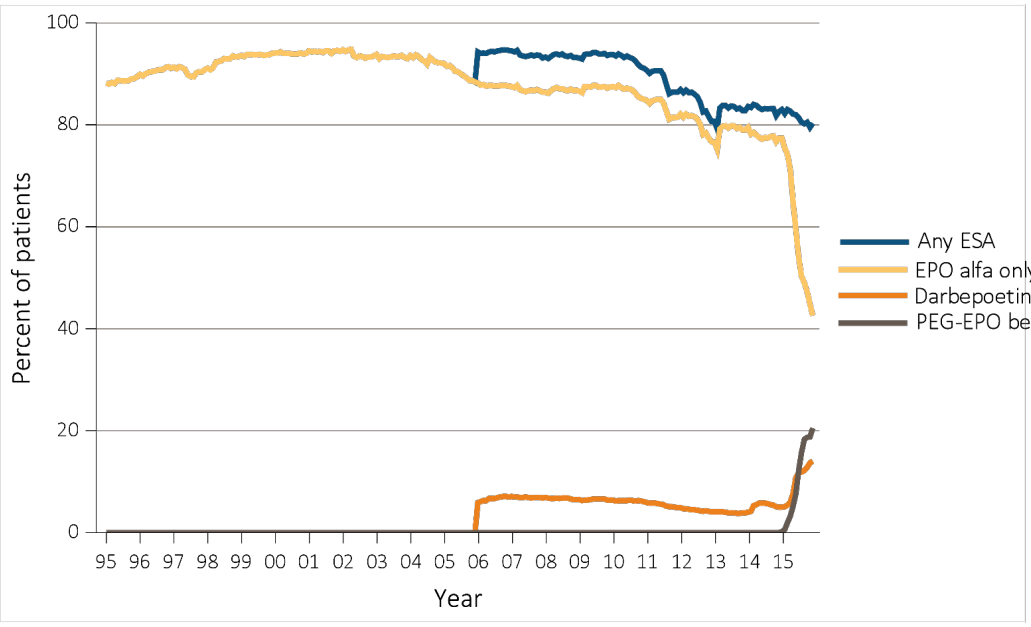
Figure 2.2 continued on next page.

vol 2 Figure 2.2 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb level and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PEG-EPO beta dose, and (d) percent ESA use monthly, Medicare claims, 1995-2015 *(continued)*

(c) Mean monthly Hgb level and mean monthly PEG-EPO beta dose



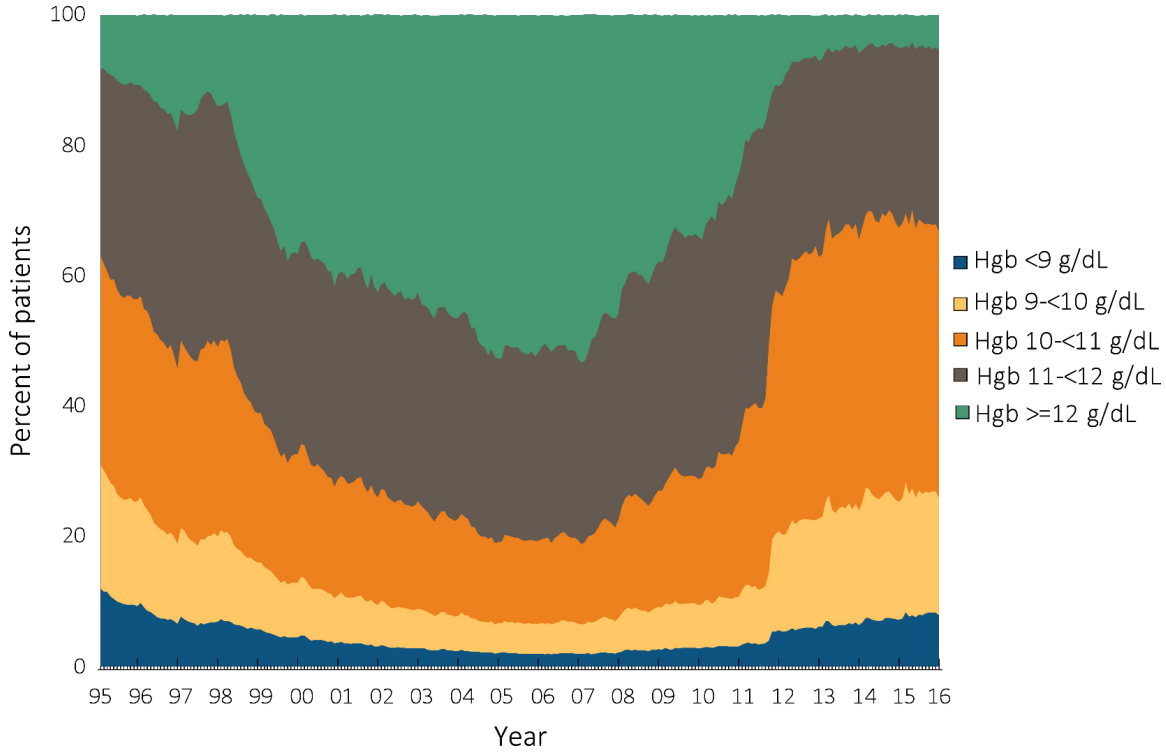
(d) Percent monthly ESA use



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a)EPO alfa- (b)darbepoetin (c)PEG-EPO beta patients on dialysis ≥ 90 days (1995-2015) or (a) mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2015 only) who, within the given month had a Hgb claim (only 1st reported Hgb value in a month were used) and were on dialysis ≥ 90 days; analyses were restricted to patients ≥ 18 years old and who had been on dialysis ≥ 90 days at the start of the month. Average weekly (EPO alfa, Figure 2.2.a) or monthly (darbepoetin and PEG-EPO beta, Figures 2.2.b and c) doses are shown for hemodialysis patients who within a given month had a corresponding ESA claim. EPO alfa dose is expressed as mean EPO alfa units per week averaged over all of a patient's EPO alfa claims w/in a given month. Darbepoetin and PEG-EPO beta dose are expressed as mean units per month over all of a patient's corresponding Darbepoetin or PEG-EPO beta claims within a given month; (d) Monthly ESA use in all hemodialysis patients who were ≥ 18 years and on dialysis ≥ 90 days. Abbreviations: EPO alfa, erythropoietin alfa; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2015, a large shift occurred in the percentage of ESA-treated adult HD patients in the highest versus lowest categories of Hgb level (Figure 2.3). Among ESA-treated patients on dialysis ≥90 days, the percentage with Hgb <10 g/dL increased from 7% in 2007 to 26% in 2015, while the percentage with Hgb ≥12 g/dL declined 10-fold from 48.5% in 2007 to 4.9% in 2015. For the group of all HD patients on dialysis ≥90 days in December 2015, 7% had Hgb <9 g/dL, 15% had Hgb of 9 to <10 g/dL, 64% had Hgb between 10-12 g/dL, and 14% had Hgb ≥12 g/dL.

vol 2 Figure 2.3 Distribution of monthly Hgb levels in ESA-treated adult hemodialysis patients on dialysis ≥90 days, Medicare claims, 1995-2015



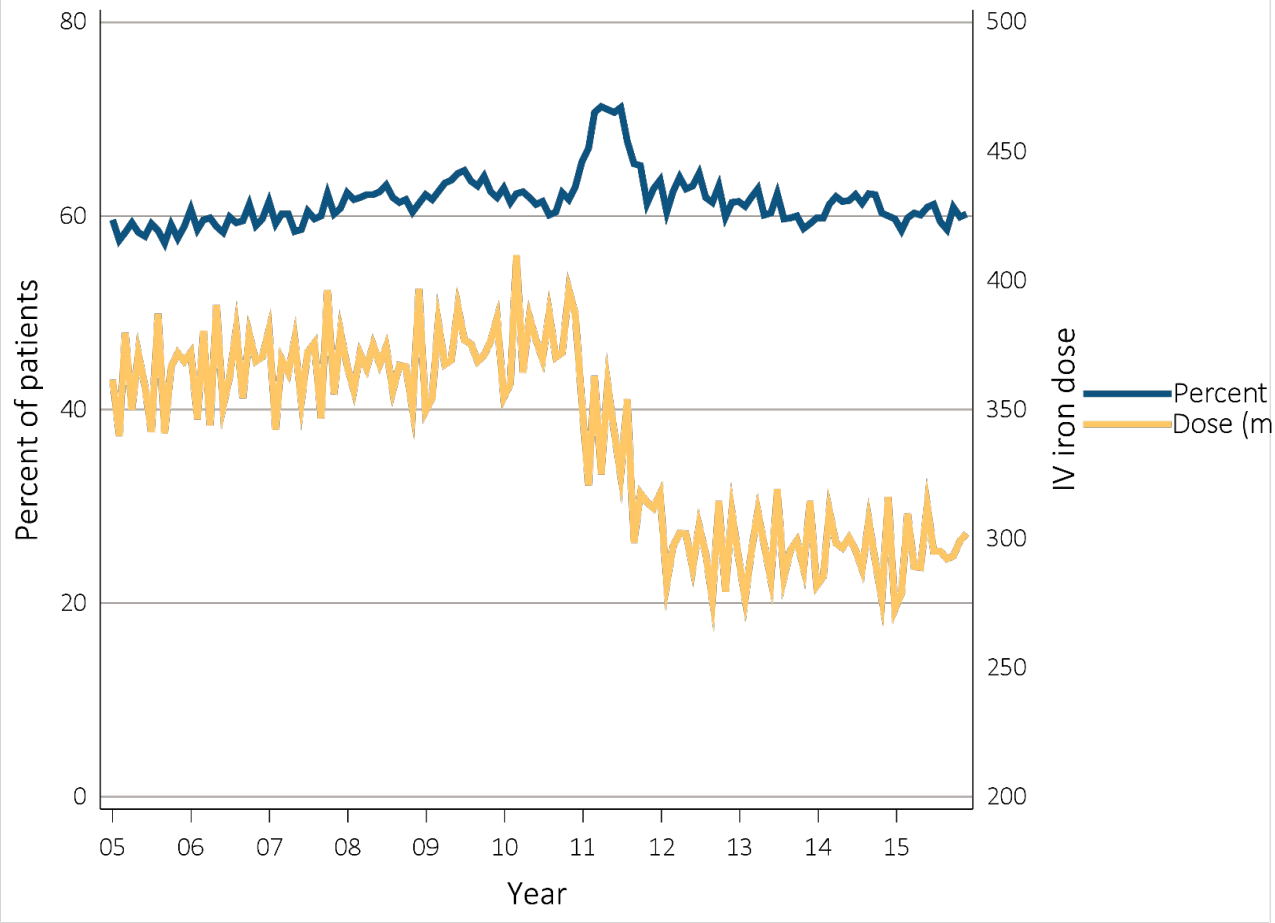
Data Source: Special analyses, USRDS ESRD Database. Distribution of monthly Hgb levels among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

IV Iron Use, IV Iron Dose, and Measures of Iron Stores in Hemodialysis Patients

Trends in IV iron use for HD patients from 2005 to 2015 are shown in Figure 2.4. IV iron use increased sharply from 60.1% in August 2010 to 71.3% by April 2011, which may have been in response to the introduction of the CMS bundled Prospective Payment System (PPS) for dialysis services that began in January 2011. However, since July 2011, IV iron use declined steadily to 60.2% by December 2015, similar to rates prior to the start of the bundled PPS in 2011.

The trend in mean monthly IV iron dose is provided for 2005 through 2015, as calculated among patients with an IV iron dose claim during the month. The average monthly dose rose from 362 mg in 2005 to 378 mg in 2010. However, coincident with the 2011 implementation of the PPS, mean monthly IV iron doses declined from 332 mg in 2011 to 297 mg in 2012, 296 mg in 2013 and 2014, and 294 mg in 2015. Thus, since 2011, both IV iron use and the average monthly IV iron dose have declined among HD patients in the U.S.

vol 2 Figure 2.4 Monthly percent IV iron use and mean monthly IV iron dose in adult hemodialysis patients on dialysis ≥90 days, Medicare claims, 2005-2015

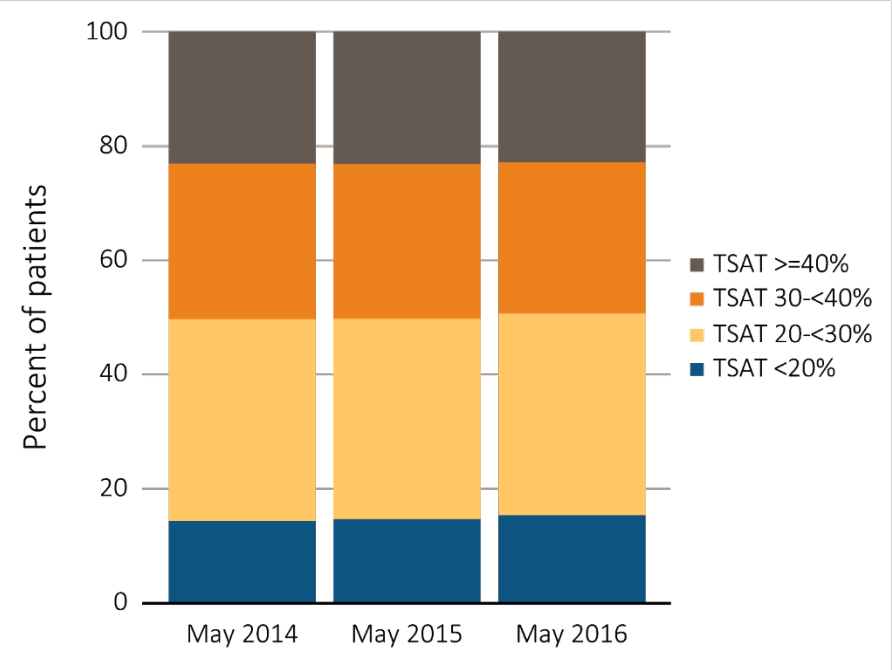


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients receiving iron during the month. Abbreviation: IV, intravenous.

U.S. dialysis units now report iron store measures, TSAT, and serum ferritin as part of CROWNWeb data collection. Reporting of these measures to CROWNWeb has increased over time. For example, serum ferritin was reported for 380,548 HD patients in 2014 versus 421,272 HD patients in 2016. Typically, reporting of TSAT levels in HD patients has been 20%-30% lower than for serum ferritin levels. TSAT was reported for 421,272 patients in 2016, compared to only 380,548 patients in 2014. Due to the changes in facility data reporting over time, interpret the trends noted below in this context.

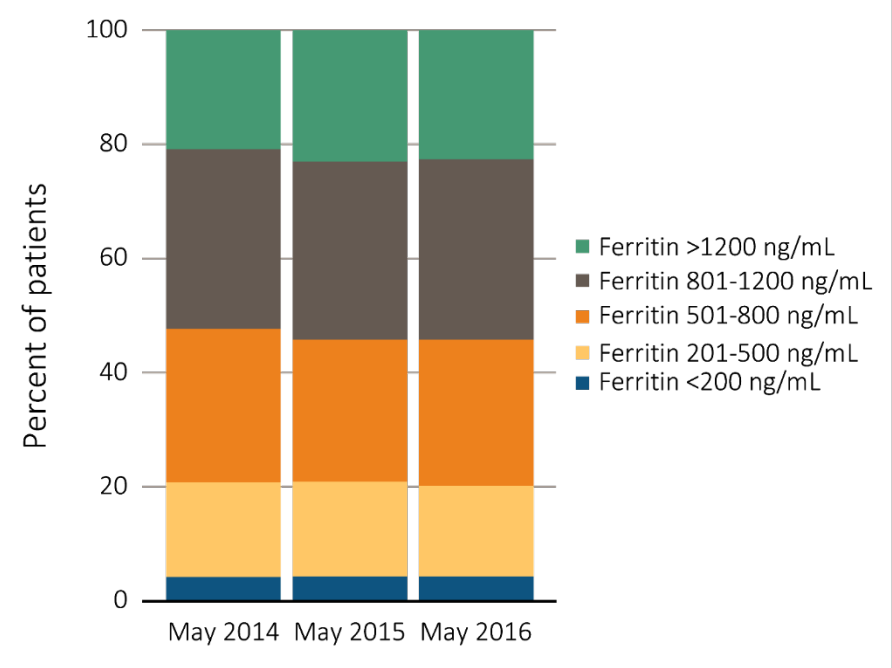
The distributions of TSAT (Figure 2.5) and serum ferritin (Figure 2.6) levels among HD patients on dialysis ≥90 days did not differ appreciably during 2014-2016. Averaged across this period, 15.4% of patients had a TSAT <20%, with 35.2%, 27.0%, and 22.4% of patients having TSAT levels of 20% to <30%, 30% to <40%, and ≥40%. The percentage of patients with TSAT <20% remained relatively stable, varying from 15.0% to 16.0%. During 2014-2016, on average 4.9% of patients had serum ferritin ≤200 ng/mL, with 16.4%, 25.8%, 31.4%, and 21.5% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. The mean serum ferritin level increased slightly, from 877 ng/mL in May 2014 to 896 in May 2016.

vol 2 Figure 2.5 Distribution of TSAT levels in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2014, May 2015 and May 2016. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 2.6 Distribution of the most recent value of serum ferritin level taken between March and May in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, 2013-2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients initiating treatment for ESRD at least 90 days before the time of measurement of serum ferritin for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Red Blood Cell Transfusions in Hemodialysis Patients

The distribution of the number of red blood cell transfusions received by Medicare HD patients, by year from 2011 through 2015, is shown in Figure 2.7.a. The results represent the entire adult HD patient population (≥18 years old) receiving at least one HD treatment during a given year. However, because some individuals did not receive HD therapy for the entire year, interpretation should be made in this light. In 2011 23.2% of HD patients received ≥1 red blood cell transfusion. This decreased to approximately 22.8% of patients in 2013 and further to 19.0% in 2015. Across this five-year period, typically 12%-14% of patients received one red blood cell transfusion per year, 4%-5% received two, 1.5%-2% received three, and 2%-3% received four or more red blood cell transfusions per year.

Trends from 2010-2015 in the percentage of HD patients with one or more red blood cell transfusions within a month are shown in Figure 2.7.b. Overall, the rate gradually declined from 3.6% in the first quarter of 2013 to 2.7% by the third quarter of 2015. Red blood cell transfusion rates were approximately 2.5 fold higher for patients on dialysis <90 days at the start of the month, compared with patients on dialysis ≥90 days. From January to November 2015, an average of 2.9% of White patients had one or more red blood cell transfusions in a month compared to 2.8% of African American/Black patients and 2.2% of those of Other or Unknown race. Note that since these differences were small, only the overall trend line is shown in Figure 2.7.b.

vol 2 Figure 2.7 Percentage of all adult hemodialysis patients (a) by number of red blood cell transfusions received in a year, and (b) with ≥1 claims for a red blood cell transfusion in a month, overall and by vintage, from Medicare claims, 2011-2015

(a) Percent of patients, by number of red blood cell transfusions received in a year

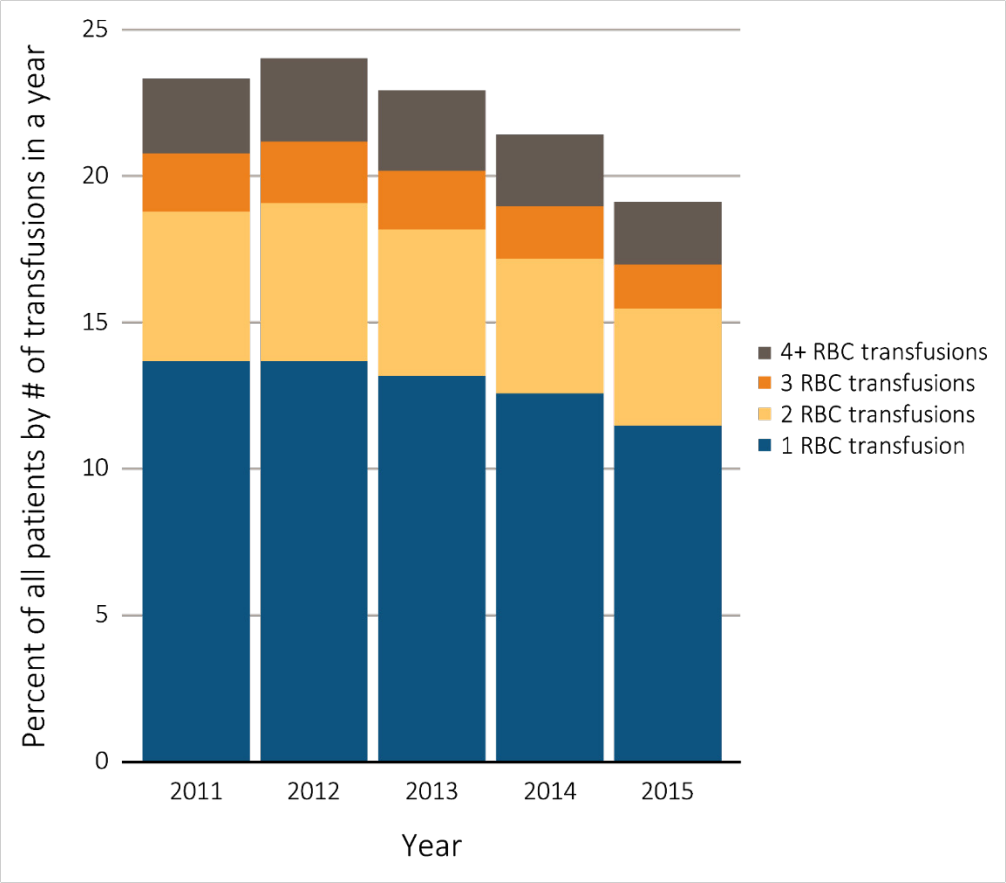
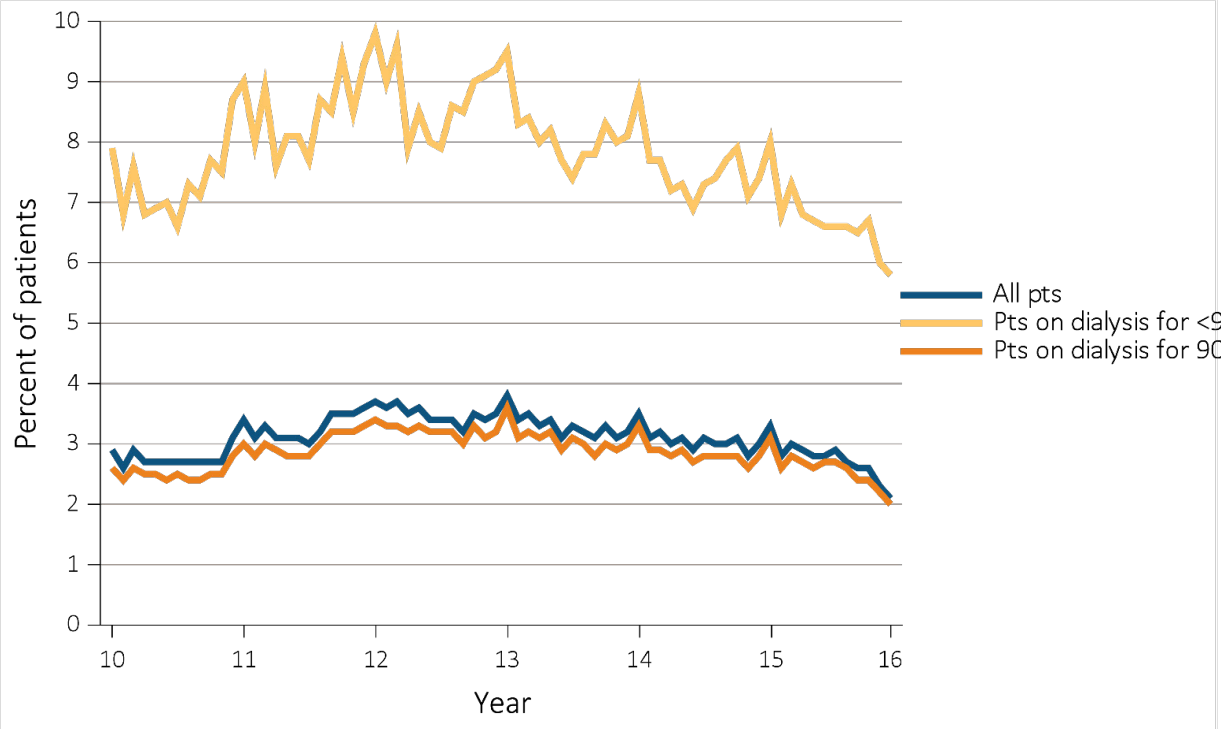


Figure 2.7 continued on next page.

vol 2 Figure 2.7 Percentage of all adult hemodialysis patients (a) by number of red blood cell transfusions received in a year, and (b) with ≥1 claims for a red blood cell transfusion in a month, overall and by vintage, from Medicare claims, 2011-2015 (*continued)*

(b) Percent of all patients, patients on dialysis <90 days, or patients on dialysis ≥90 days, who had one or more claims for a red blood cell transfusion in a month



Data Source: Special analyses, USRDS ESRD Database. The percentage of hemodialysis patients ≥18 years old at the start of the month with ≥1 red blood cell transfusion claims in a given month among hemodialysis patients having a claim for at least one dialysis session during the month. Additional analysis of RBC transfusion claims completed for patients on dialysis for < 90 days or ≥ 90 days. Abbreviation: RBC, red blood cell.

Hgb Levels, ESA Use, and Dose in Peritoneal Dialysis Patients

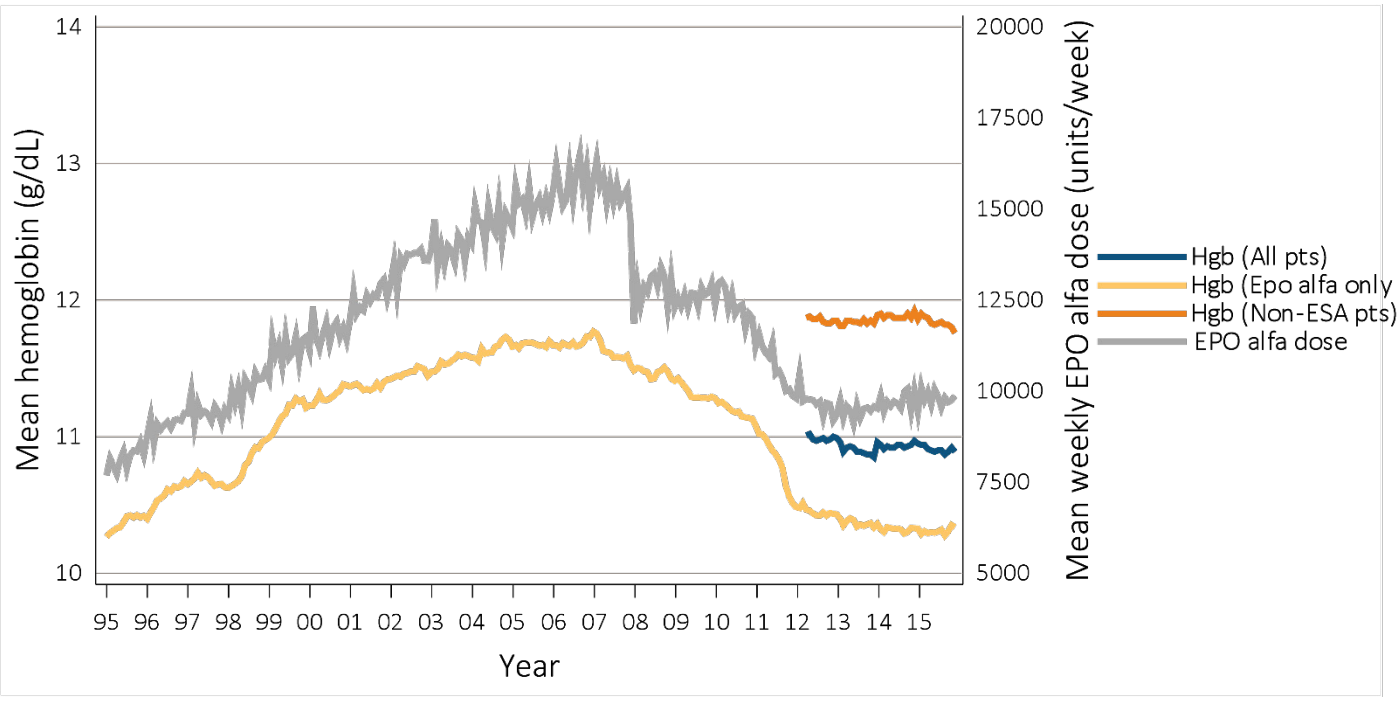
Claims data indicate that mean Hgb levels have declined substantially in ESA-treated PD patients since peaking near 11.8 g/dL in January 2007 (Figure 2.8.a). During 2011, patients' mean Hgb levels declined by 0.6 g/dL, from 11.1 g/dL to 10.5 g/dL. This was a larger decline, with a lower achieved mean Hgb level than that seen during 2011. Since then, levels have continued to decline to a mean monthly Hgb of 10.3 g/dL in 2015 among ESA-treated PD patients on dialysis ≥90 days. In contrast, in 2015, mean monthly Hgb values of 10.9 g/dL were seen for *all* PD patients on dialysis ≥90 days, and 11.8 g/dL for non-ESA treated patients. Analyses of CROWNWeb data have indicated a similar mean Hgb level of 10.9 g/dL for *all* PD patients in May 2016.

The percentage of PD patients on dialysis ≥90 days who had an ESA claim during any single month was stable during 2015, at 61%-64% (Figure 2.8.b). From December 2014 to December 2015, there was a large shift in the type of ESA prescribed to Medicare patients, with 57.1% and 4.5% prescribed EPO-alfa and darbepoetin in December 2014, to 40.4%, 9.2%, and 9.2% prescribed EPO alfa, darbeopoetin, and PEG-EPO beta in December 2015.

Among PD patients on dialysis ≥90 days, mean weekly EPO alfa dose was on average 0.8% higher in 2015 than in 2014, but was relatively stable throughout 2015. When calculated for the prevalent cross-section of PD patients on dialysis ≥90 days in each month of 2015, and then averaged across the 12 months in 2014, the mean weekly EPO alfa dose was 9,795 ± 57 units per week in 2015. The rapid, large decline (Figure 2.8.a) and rise in percent ESA use seen at the start of 2008 (Figure 2.8.b) may be related to a change in the reporting codes for EPO alfa-related claims submission at that time.

vol 2 Figure 2.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb and mean monthly darbepoetin dose, and (c) percent ESA use monthly, Medicare claims, 1995-2015

(a) Mean monthly Hgb level and mean weekly epoetin alfa dose



(b) Mean monthly Hgb level and mean monthly darbepoetin dose

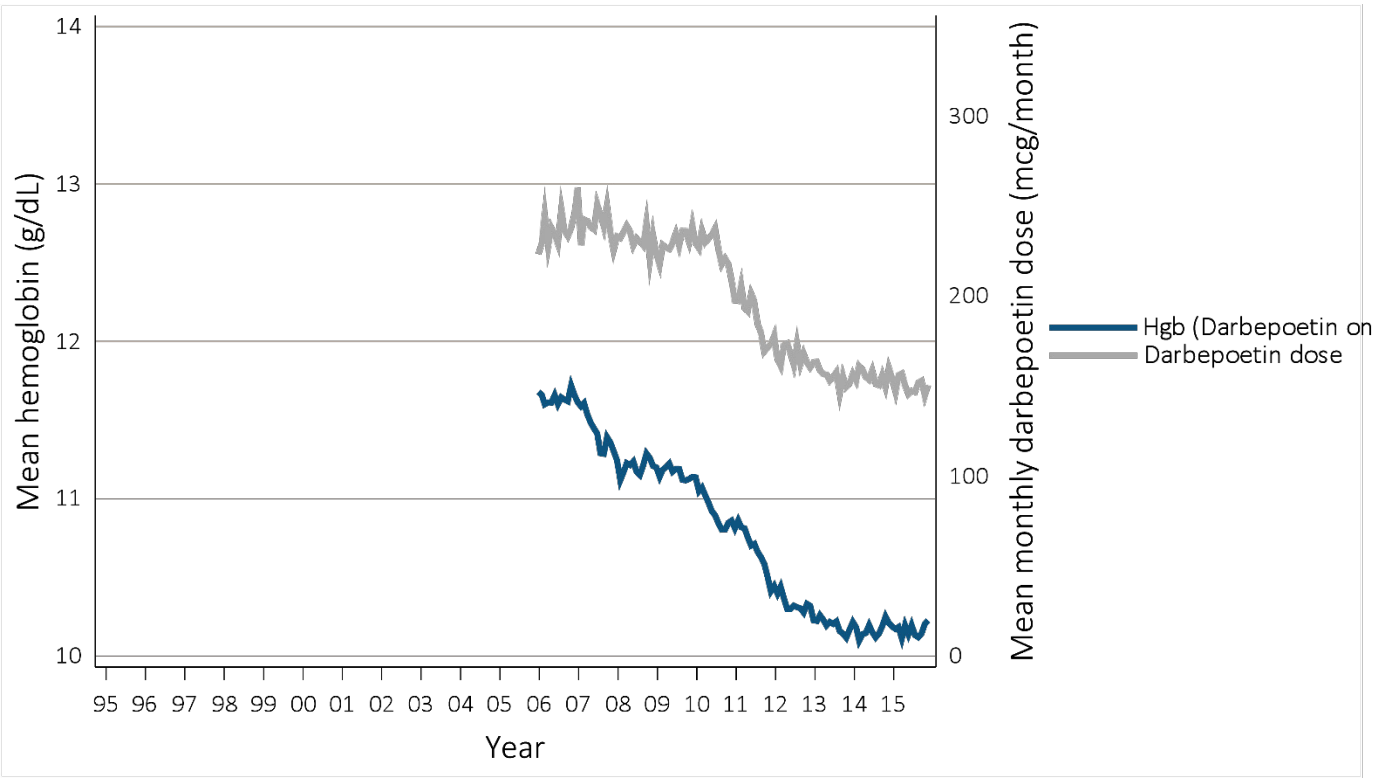
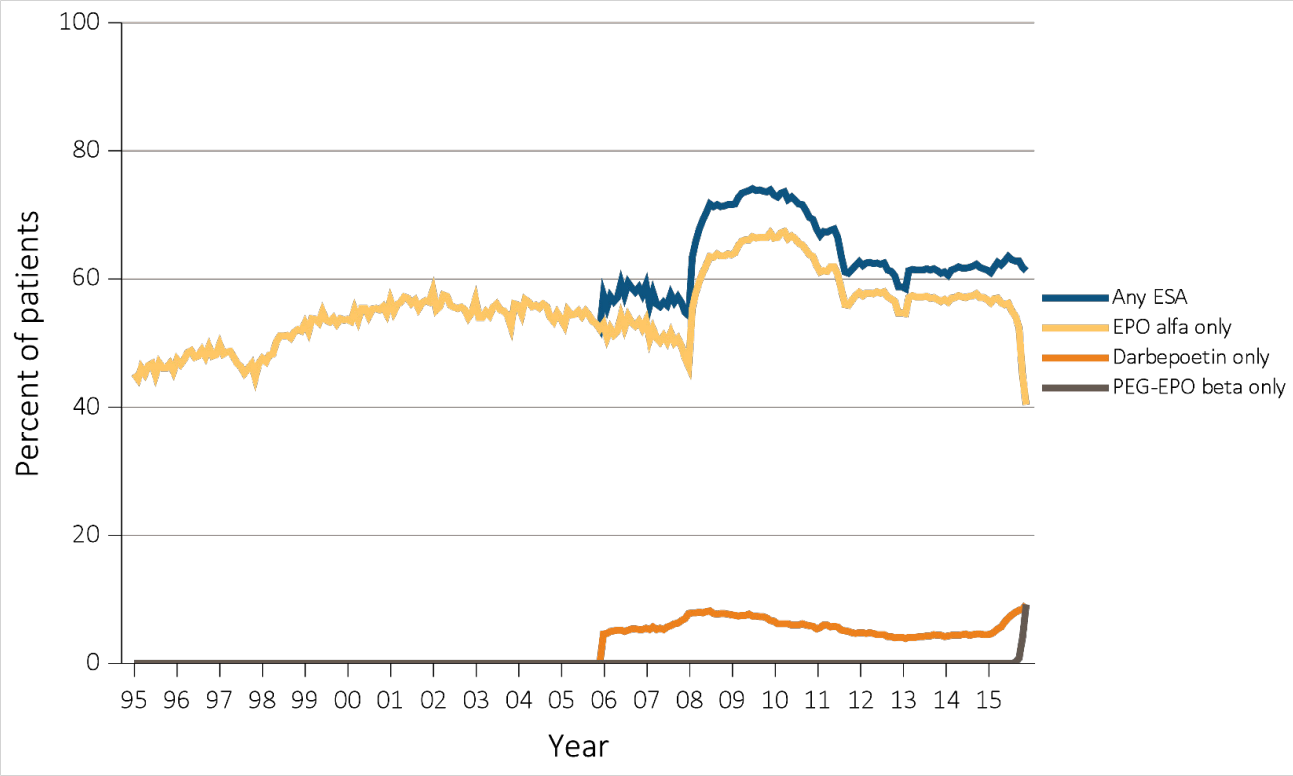


Figure 2.8 continued on next page.

vol 2 Figure 2.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb and mean monthly darbepoetin dose, and (c) percent ESA use monthly, Medicare claims, 1995-2015 *(continued)*

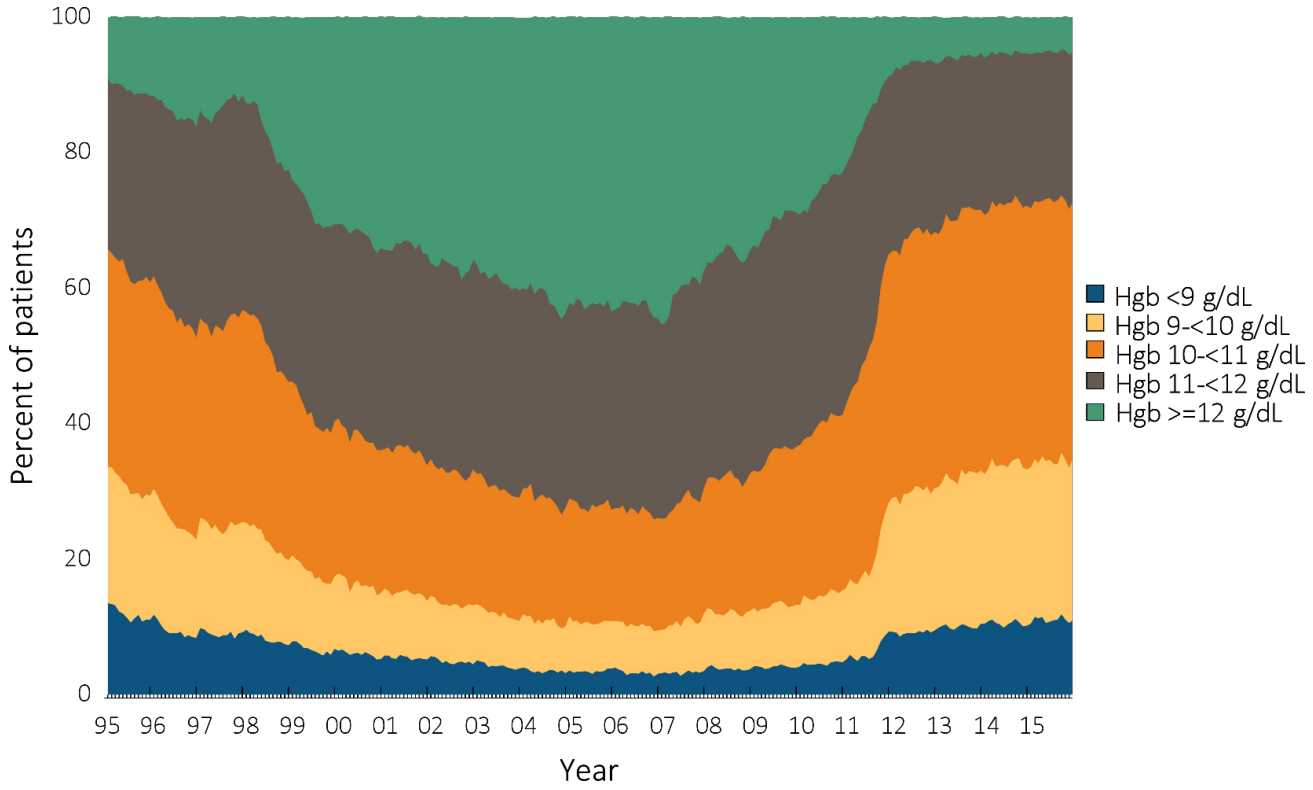
(c) Percent ESA use monthly



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a) EPO alfa- and (b) darbepoetin on dialysis ≥ 90 days (1995-2015) or (b) mean monthly Hgb level among all adult peritoneal dialysis patients (April 2012 to December 2015 only) who, within the given month, had a Hgb claim (only 1st reported Hgb value in a month were used) and were on dialysis ≥ 90 days; analyses were restricted to patients ≥ 18 years old and who had been on dialysis ≥ 90 days at the start of the month. Average weekly (EPO alfa, Figure 2.2.a) or monthly (darbepoetin, Figure 2.2.b) doses are shown for peritoneal dialysis patients who within a given month had a corresponding ESA claim. EPO alfa dose is expressed as mean EPO alfa units per week averaged over all a patient's EPO alfa claims within a given month. Darbepoetin dose is expressed as mean units per month over all of a patient's corresponding Darbepoetin claims within a given month. PEG-EPO beta dose and Hgb Figure excluded due to small numbers. (c) Monthly ESA use (EPO alfa, Darbepoetin, or PEG-EPO beta) in all hemodialysis patients who were ≥ 18 years and on dialysis ≥ 90 days. Abbreviations: EPO alfa, erythropoietin alfa; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2014, a large shift occurred in the percentage of patients in the highest versus lowest Hgb concentration categories (Figure 2.9). Among ESA-treated adult patients on PD ≥90 days, the percentage with Hgb <10 g/dL increased from 11% in 2007 to 35% in 2015, while the percentage with Hgb ≥12 g/dL declined from 37.5% in December 2007 to 5.3% in December 2015. Among all PD patients on dialysis ≥90 days in December 2015, 7.6% had Hgb <9 g/dL, 16.7% had Hgb of 9 to <10 g/dL, 55.1% had Hgb between 10-12 g/dL, and 20.5% had Hgb ≥12 g/dL.

vol 2 Figure 2.9 Distribution of monthly Hgb levels in ESA-treated adult peritoneal dialysis patients on dialysis ≥90 days, Medicare claims, 1995-2015

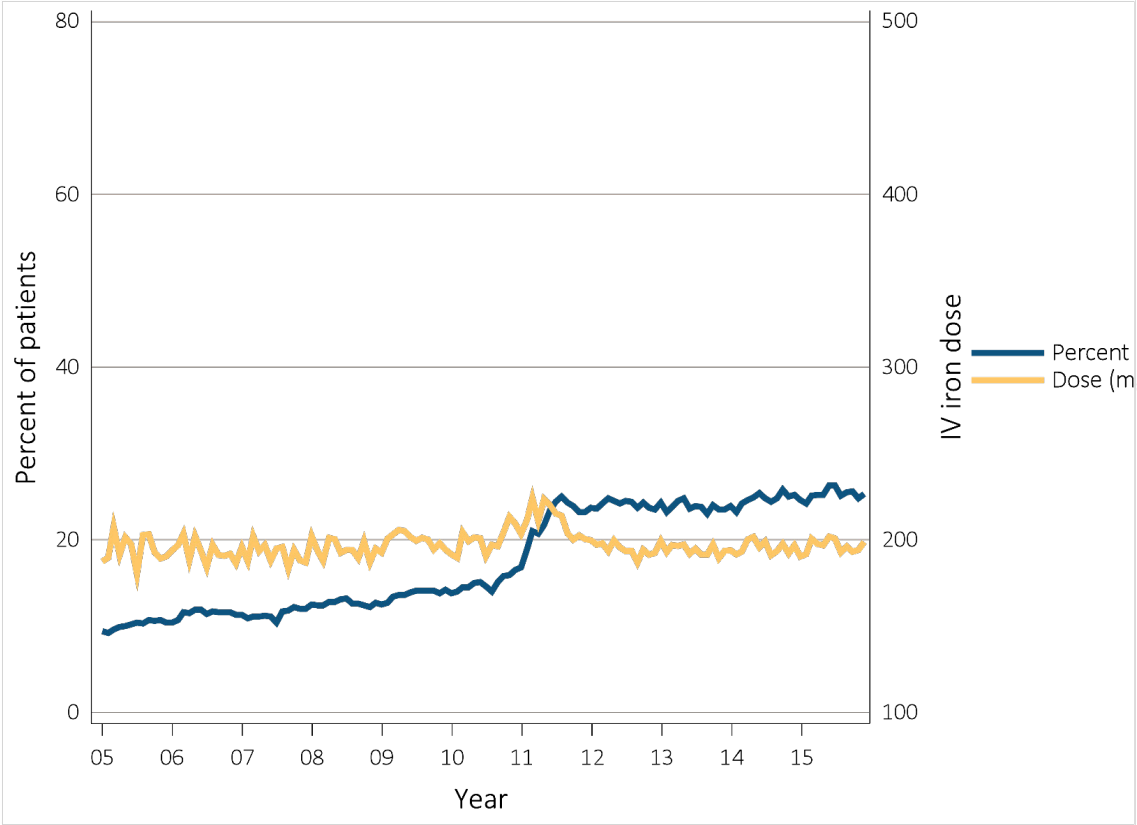


Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

IV Iron Use, IV Iron Dose, and Measures of Iron Stores in Peritoneal Dialysis Patients

Trends in IV iron use by PD patients are shown from 2005 through 2015 (Figure 2.10). IV iron use increased sharply from 14.0% in August 2010 to 25.0% by August 2011, which may have been in response to the start of the CMS bundled prospective payment system (PPS) for dialysis services in January 2011. As of the final quarter of 2015, IV iron use among PD patients on dialysis ≥90 days remained higher, at 25.2%. The mean monthly IV iron dose rose steadily from 194 mg in 2005 to 211 mg in 2011. However, coincident with the 2011 implementation of the PPS, average mean monthly IV iron doses declined to 195-196 mg in years 2012-2015. Thus, since 2011, the rate of IV iron use in the U.S. has increased, while the average monthly IV iron dose among patients prescribed iron has declined.

vol 2 Figure 2.10 Monthly IV iron use and mean monthly IV iron dose in adult peritoneal dialysis patients on dialysis ≥90 days, Medicare claims, 2005-2015

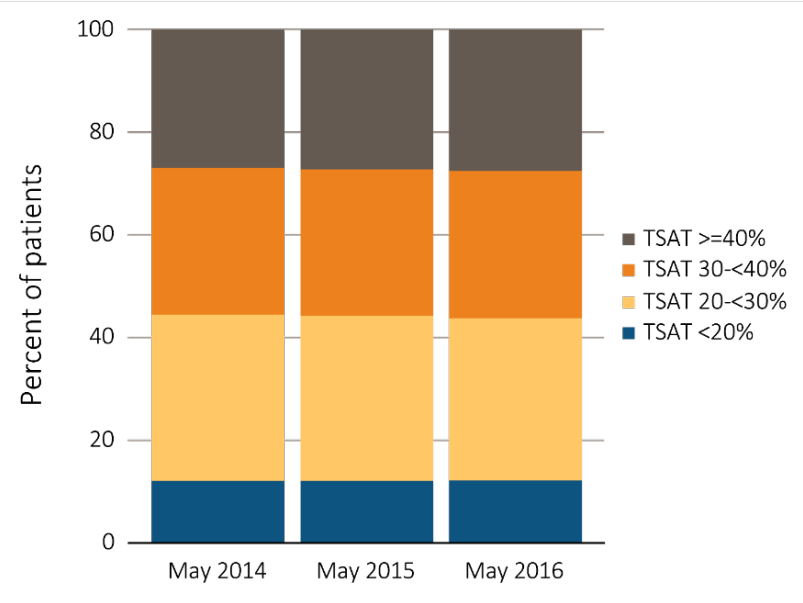


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients receiving iron during the month. Abbreviation: IV, intravenous.

As mentioned previously, reporting of iron store measures, TSAT, and serum ferritin has gradually increased over time. For example, when including the most recent value reported in the prior three months, serum ferritin was reported for 33,743 PD patients in 2014 versus 43,090 PD patients in 2016. TSAT was reported for 35,700 PD patients in 2014 compared to 44,153 PD patients in 2016.

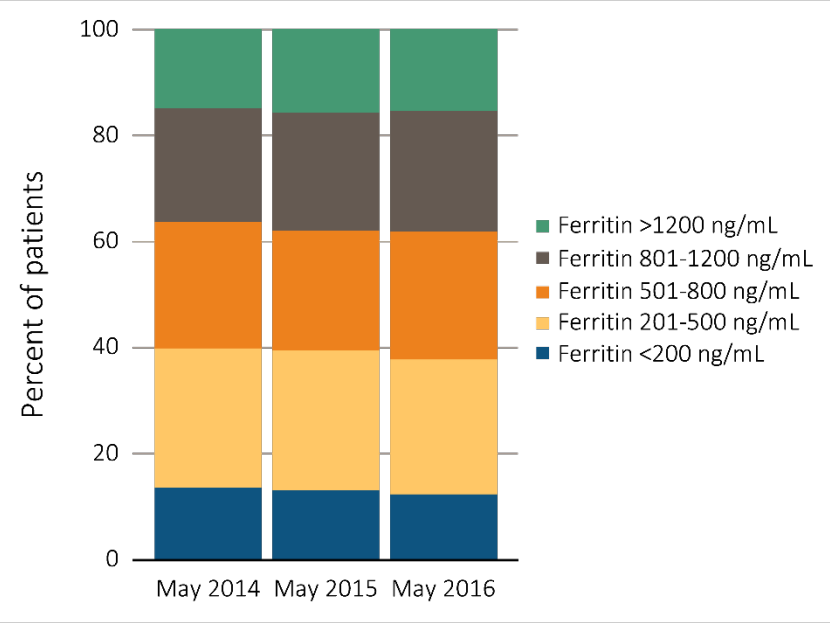
When interpreting the trends described below, it is helpful to bear in mind the changes in facility data reporting over time. Across the three mid-year cross-sections shown in Figures 2.11 and 2.12, the distribution of TSAT and serum ferritin levels among PD patients on dialysis ≥90 days did not differ appreciably. Averaged across the three years, 12.7% of patients had a TSAT<20%, with 32.1%, 28.6%, and 26.6% of patients having levels of 20% to <30%, 30% to <40%, and ≥40%. Across the 2014-2016 period, on average, 13.6% of patients had a serum ferritin ≤200 ng/mL, with 26.0%, 23.5%, 22.1%, and 14.7% of patients having levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. The mean serum ferritin level increased slightly from 706 to 720 ng/mL during the May 2014 to May 2016 cross-section.

vol 2 Figure 2.11 Distribution of TSAT levels in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 90 days at the time of measurement of TSAT level for that year, ≥18 years old as of May 1st of that year, and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 2.12 Distribution of the most recent serum ferritin level taken between March and May in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 90 days at the time of measurement of serum ferritin for that year, ≥18 years old as of May 1 of that year, and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Red Blood Cell Transfusions in Peritoneal Dialysis Patients

Figure 2.13.a shows the distribution of the number of red blood cell transfusions received by PD patients from 2011 through 2015. The results are for those aged 18 years or older who received at least one PD treatment during a given year. However, because some individuals did not receive PD for the entire year, interpret results with this in mind.

In 2011, 22.6% of PD patients received one or more red blood cell transfusions. This increased to approximately 23% of patients in 2012, declined again to 21.7% in 2013, and to 19.8% of PD patients in 2014. In 2015, only 18% of PD patients received one or more red blood cell transfusions. Across this five-year period, typically 12%-13% of PD patients received one red blood cell transfusion per year, 4%-5% received two per year, 1.5%-2% received three, and 2%-3% received four or more.

Trends in the percentage of PD patients receiving one or more red blood cell transfusions within a month during 2010-2015 are shown in Figure 2.13.b. Overall the percent of PD patients receiving any red blood cell transfusions in a month has gradually declined from 3.3% in the first quarter of 2013 to 2.4% by the third quarter of 2015. When comparing red blood cell transfusion rates among incident versus prevalent PD patients, transfusion rates were only slightly higher for patients on PD <90 days at the start of the month compared with those on PD ≥90 days. From January to November 2015, on average 2.4% of White patients had one or more red blood cell transfusions in a month compared to 2.7% of Black patients and 2.0% of those of Other or Unknown race. Note that as these differences were small, only the overall trend line is shown in Figure 2.13.b.

vol 2 Figure 2.13 Percentage of all adult peritoneal dialysis patients (a) by number of red blood cell transfusions received in a year, and (b) with ≥1 claims for a red blood cell transfusion in a month, from Medicare claims data overall, within 90 days and after at least 90 days of first PD session, 2010-2015

(a) Number of red blood cell transfusions received in a year

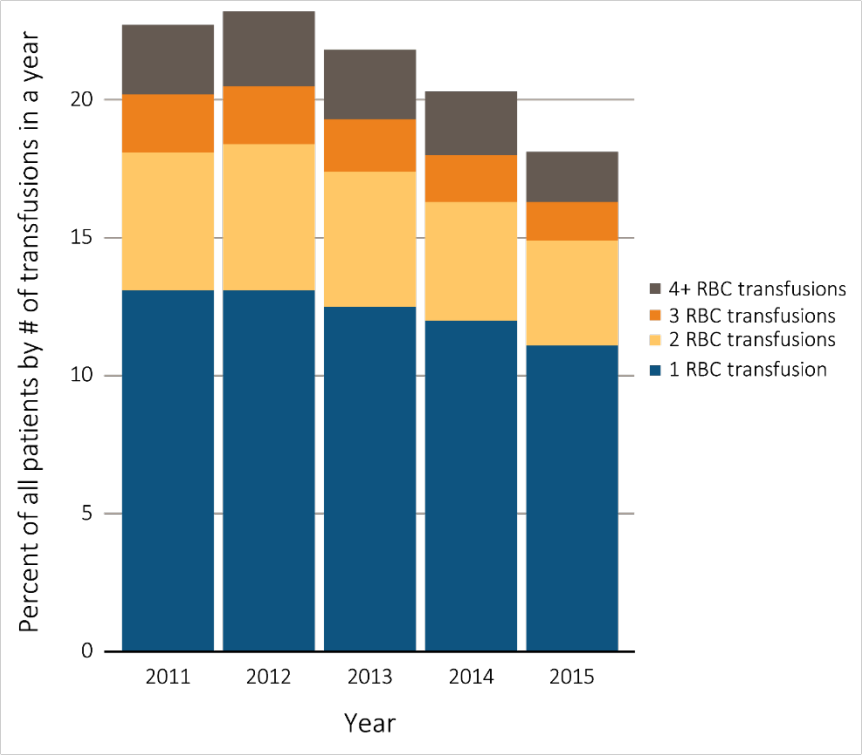
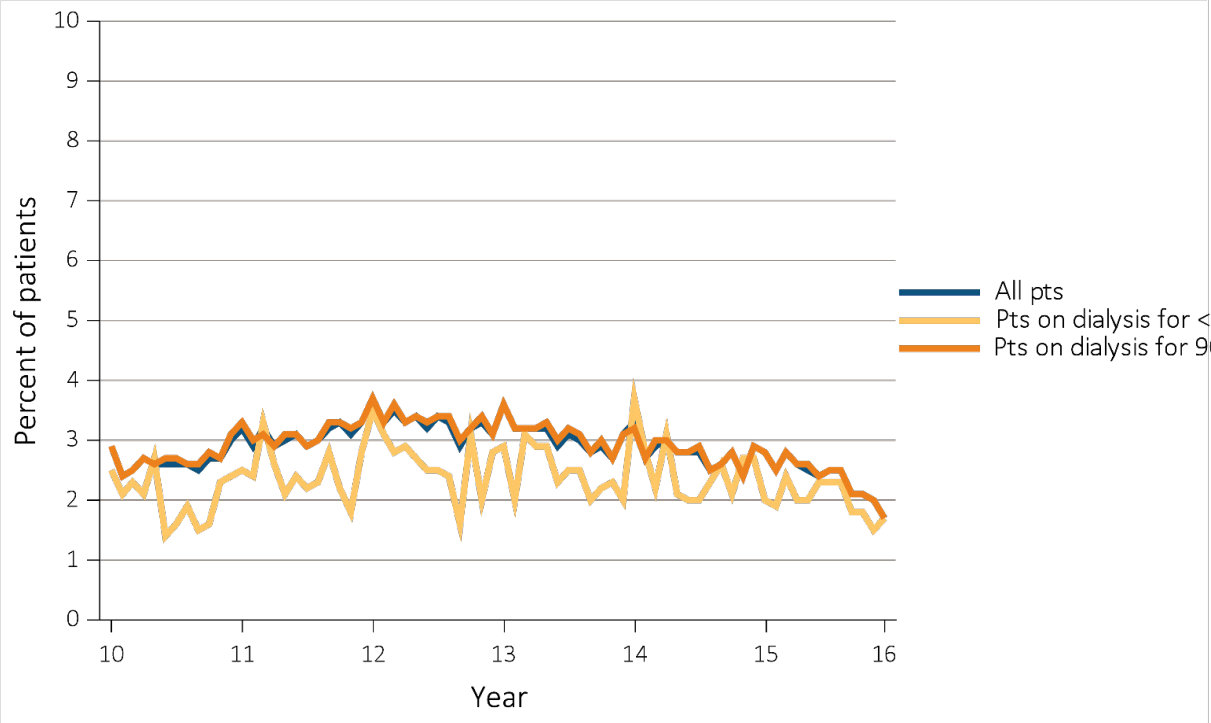


Figure 2.13 continued on next page.

vol 2 Figure 2.13 Percentage of all adult peritoneal dialysis patients (a) by number of red blood cell transfusions received in a year, and (b) with ≥1 claims for a red blood cell transfusion in a month, from Medicare claims data overall, within 90 days and after at least 90 days of first PD session, 2010-2015

(b) Percent of all patients, patients on dialysis <90 days, or patients on dialysis ≥ 90 days, who had ≥1 claim for a red blood cell transfusion in a month



Data Source: Special analyses, USRDS ESRD Database. The percentage of peritoneal dialysis patients with ≥1 red blood cell transfusion claims in a given month was among peritoneal dialysis patients having a claim for at least one dialysis session during the month, and who were ≥18 years old at the start of the month. Additional analysis of RBC transfusion claims completed for patients on dialysis for < 90 days or ≥ 90 days. Abbreviation: RBC, red blood cell.

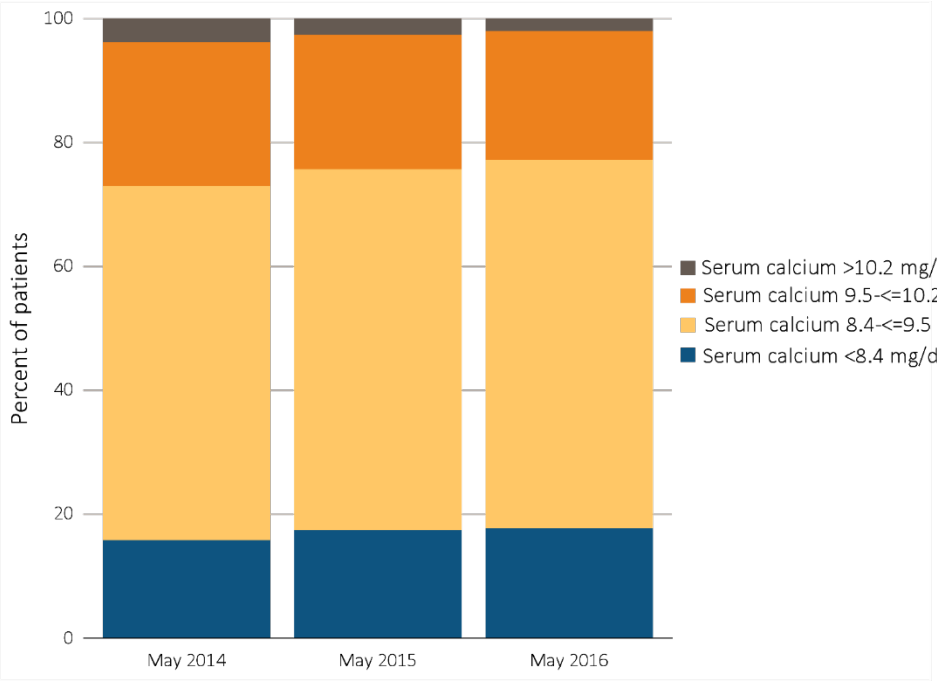
Mineral and Bone Disorders

Evidence from basic scientific and epidemiological studies supports the role of abnormalities in markers of mineral and bone metabolism in the pathogenesis of vascular calcifications and cardiovascular disease—major causes of increased hospital admissions and mortality in the ESRD population. Specifically, elevated levels of calcium and phosphorus have been associated with increased cardiovascular events and mortality. Very low calcium and phosphorus levels have also been associated with poor outcomes. While low calcium and phosphorus levels may reflect, in part, poor nutritional status, it is also possible that they result from inappropriate treatment. Based on these observations, current Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines (KDIGO, 2017: Chapter 4.1) suggest that chronic dialysis patients maintain serum calcium and phosphorus levels in the normal reference range.

Serum Calcium

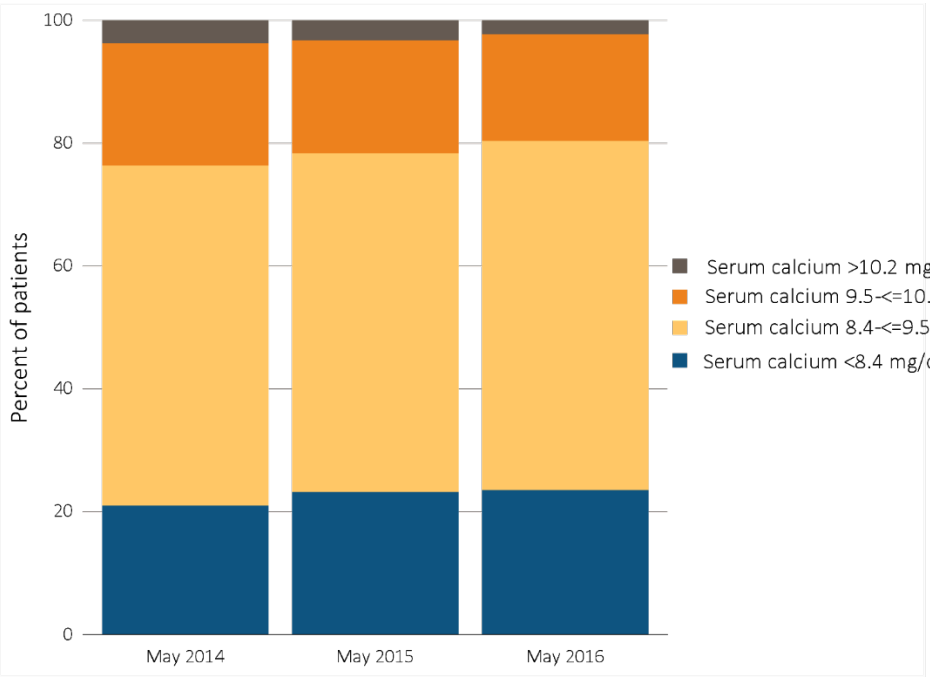
The distributions of serum calcium levels (based on the value in May of the indicated calendar year) among adult HD and PD patients are shown in Figures 2.14 and 2.15. Between 2014 and 2016, no substantial change was observed in serum calcium distribution. The majority of 2016 patients (HD: 59.5%, PD: 56.9%) had calcium levels within the usual normal reference range (8.4-9.5 mg/dL), while a very small percentage (HD: 1.7%, PD: 1.9%) had serum calcium levels >10.2 mg/dL, a cut point that reflects the quality measure that is currently included in the QIP and DFC programs. The May 2016 prevalence of very low calcium levels (<8.4 mg/dL) was higher in patients on PD, at 23.9%, than for HD at 18.1%, likely due to differences in serum albumin levels related to dialytic treatment.

vol 2 Figure 2.14 Distribution of serum calcium levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2014, 2015, and 2016



Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 2.15 Distribution of serum calcium levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2014, 2015, and 2016

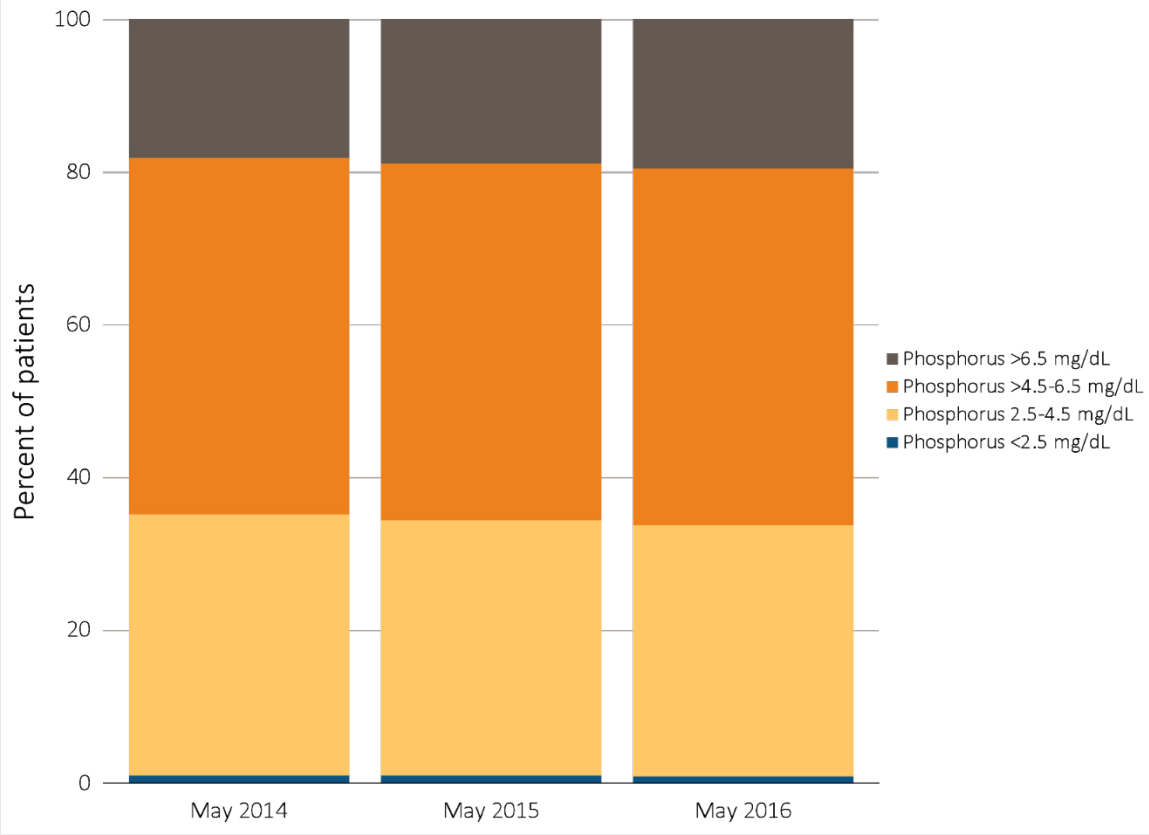


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2014, 2015 and 2016. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Serum Phosphorus

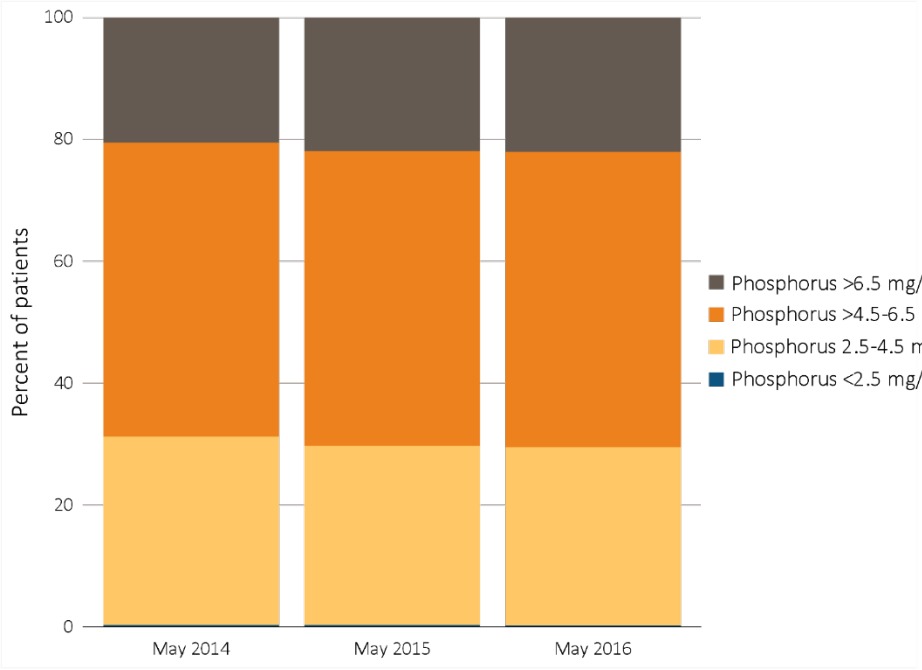
Figures 2.16 and 2.17 illustrate the distributions of serum phosphorus levels among adult HD and PD patients. Between 2014 and 2016, a slight increase in mean serum phosphorus was observed both in HD and PD patients (HD: from 5.2 to 5.3 mg/dL; PD: from 5.4 to 5.5 mg/dL). KDIGO guidelines (KDIGO, 2009) recommend maintaining phosphorus levels within the laboratory reference range, typically between 2.5 and 4.5 mg/dL. Among HD patients in May 2016, approximately two-thirds (65.9%) had serum phosphorus >4.5 mg/dL. This percentage was even higher among patients on PD (70.1%), indicating a clear opportunity for improvement in serum phosphorus control. Prior studies have shown that patients having low serum phosphorus levels (<2.5 mg/dL) have elevated mortality risk and a high likelihood of malnutrition. In cross-sectional 2014 to 2016 CROWNWeb data, only 1.3%-1.4% of HD patients and 0.6%-0.7% of PD patients had serum phosphorus levels of <2.5 mg/dL.

vol 2 Figure 2.16 Distribution of serum phosphorus levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2014, May 2015, and May 2016. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum phosphorus for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 2.17 Distribution of serum phosphorus levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWEB data, May 2014, 2015, and 2016



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2014, May 2015, and May 2016. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum phosphorus for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Preventive Care

Diabetes Mellitus

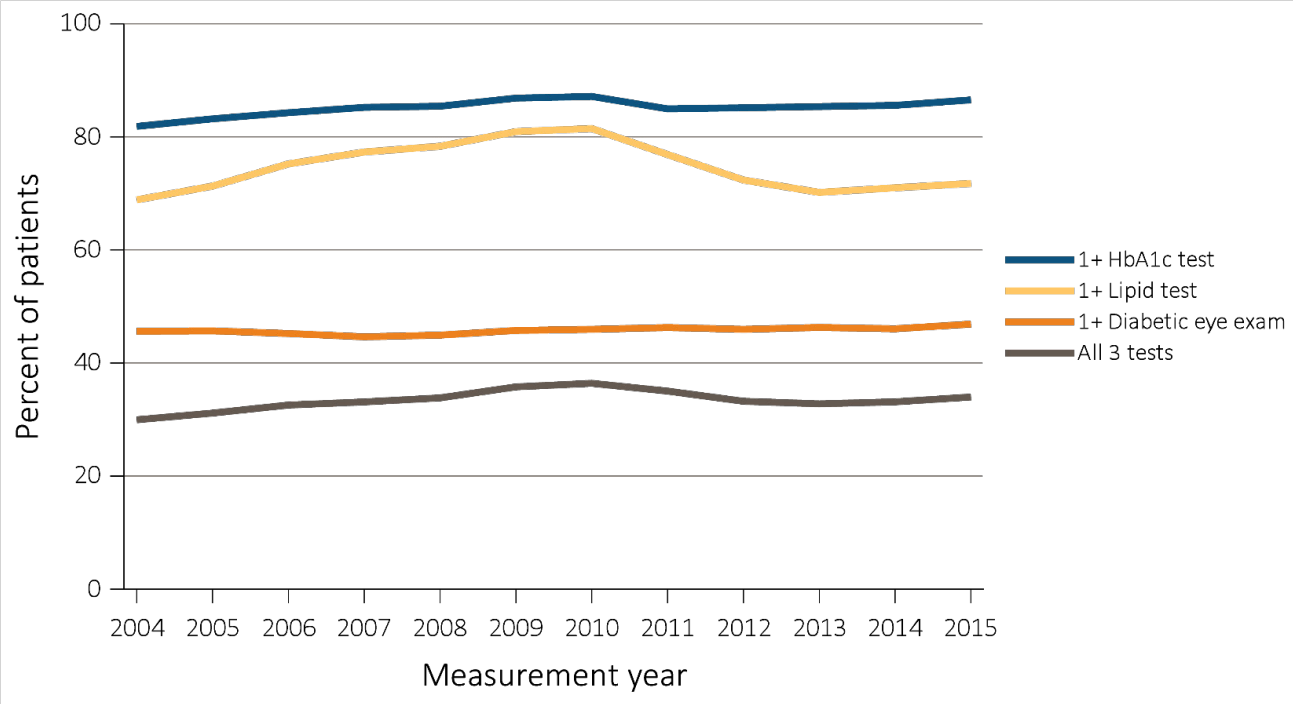
Recommendations for glycemic and lipid monitoring, treatment, and target levels in diabetic patients with ESRD are controversial. In preventing vision loss, however, the role of regular dilated eye exams and timely treatment is well established.

From 2004 to 2015, Medicare claims showed a slight increase in the percentage of ESRD patients with diabetes who received at least one glycosylated hemoglobin test (HbA1c; 81.9% in 2004 to 85.6% in 2015). The percentage of ESRD patients with diabetes who received at least one lipid test increased steadily from 2004 to 2010 (68.9% to 81.5%), decreased between 2010 and 2013 (81.5% to 71.2%), and since 2013 has remained stable at approximately 72% (71.8% in 2015; Figure 2.18). The National Committee for Quality Assurance Comprehensive Diabetes Care data also shows an increase in testing over this period in the privately insured population with diabetes—89-90% received at least one HbA1c test in 2015. In the Medicare population with diabetes, 93% received at least one HbA1c test in 2015. In 2014, 81-85% of privately insured people with diabetes received at least on LDL-C test and 89.0% of people in the Medicare population with diabetes received at least one LDL test. NCQA retired its LDL-C screening measure in 2015.

The decrease in HbA1c testing may reflect an increasing awareness of the limitations of HbA1c as an indicator of average glycemia in diabetic patients with ESRD. The reason for the decrease in lipid testing rates is unclear, but may have been influenced by relevant publications. Wanner et al. (2005) and Fellstrom et al. (2009) demonstrated a lack of effect of statin therapy on fatal and nonfatal cardiovascular outcomes in patients undergoing HD. In addition, the American College of Cardiology/American Heart Association introduced guidelines that recommended periodic, rather than annual lipid monitoring.

In 2015, 46.9% of patients had at least one diabetic eye exam, a low but constant rate over the past decade. This did not meet the *Healthy People 2020* target of 58.7%. A similar pattern exists for the patients receiving all three tests—approximately 34% in the most recent data year. Thus, there remains a substantial opportunity for quality improvement in preventive care for DM in this population.

vol 2 Figure 2.18 Diabetes-related care among ESRD patients with diabetes mellitus aged 18-75 years, Medicare claims, 2004-2015



Data Source: Special analyses, USRDS ESRD Database. Point prevalent Medicare ESRD patients aged 18 to 75 years with a diagnosis claim for diabetes mellitus in the previous year; diabetes-related care in the measurement year. Abbreviations: ESRD, end-stage renal disease; HbA1c, glycosylated hemoglobin.

VACCINATION

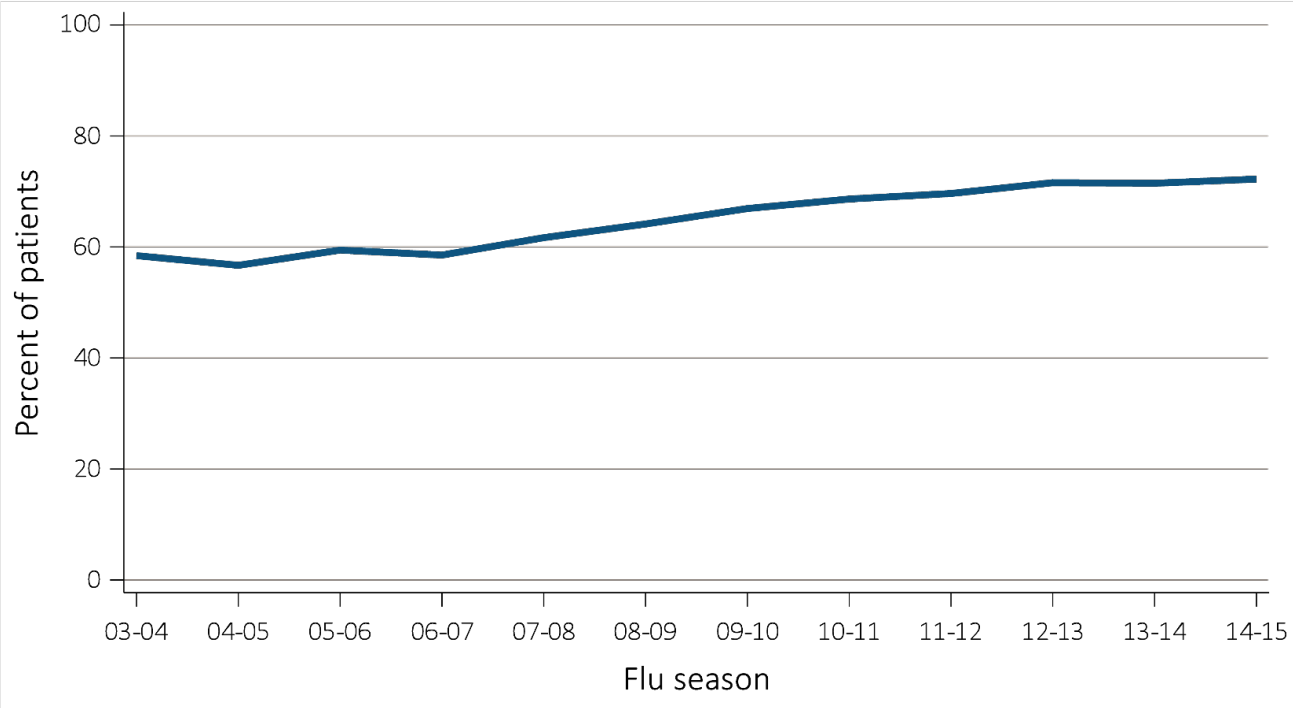
It is recommended that all ESRD patients receive an annual influenza vaccination. To account for early or later vaccinations, we define seasonal influenza vaccination more broadly than the typical October through March influenza season by including the period of August 1 through April 30. Based on Medicare claims data, the percentage of ESRD patients receiving influenza vaccination has slowly improved over the past decade, rising from 56.7% in the 2004-2005 season to 72.2% in the 2014-2015 season (Figure 2.19.a). However, it remains below the *Healthy People 2020* target of 90%.

The percentage of patients vaccinated was highest in older age groups, with only 39.7% of ESRD patients aged 0-21 years receiving an influenza vaccine in the 2014-2015 season; this continued a downward trend seen since the 2012-2013 season (Figure 2.19.b). This trend may in part relate to the higher, and increasing, transplant rates in the age 0-21 years group, as vaccination rates are lower among transplant patients (Figure 2.19.e).

The percentage of patients vaccinated was similar in the most recent data years across both race and ethnicity groups, although slightly lower among Blacks at 71.0% in the 2014-2015 season (Figures 2.19.c and 2.19.d). By modality, HD patients were vaccinated at the highest frequency—78.1% in the most current data—compared with 77.2% of PD patients and 51.8% of kidney transplant patients (Figure 2.19.e). The percentage vaccinated may be lower in transplant patients in part because vaccination is often delayed for several months after a new transplant due to concerns regarding an ineffective immune response or the possibility of triggering an acute rejection episode. These percentages as reported may be underestimates, as they were derived from claims data that may not completely capture all vaccination events. Future Annual Data Reports will utilize CROWNWeb data that should provide information that is more complete, including status for other recommended vaccinations, such as for pneumococcus and hepatitis B.

vol 2 Figure 2.19 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), (a) overall, (b) by age, (c) by race (d) by ethnicity, and (e) by ESRD treatment modality, Medicare data, 2003-2015

(a) Overall



(b) Age

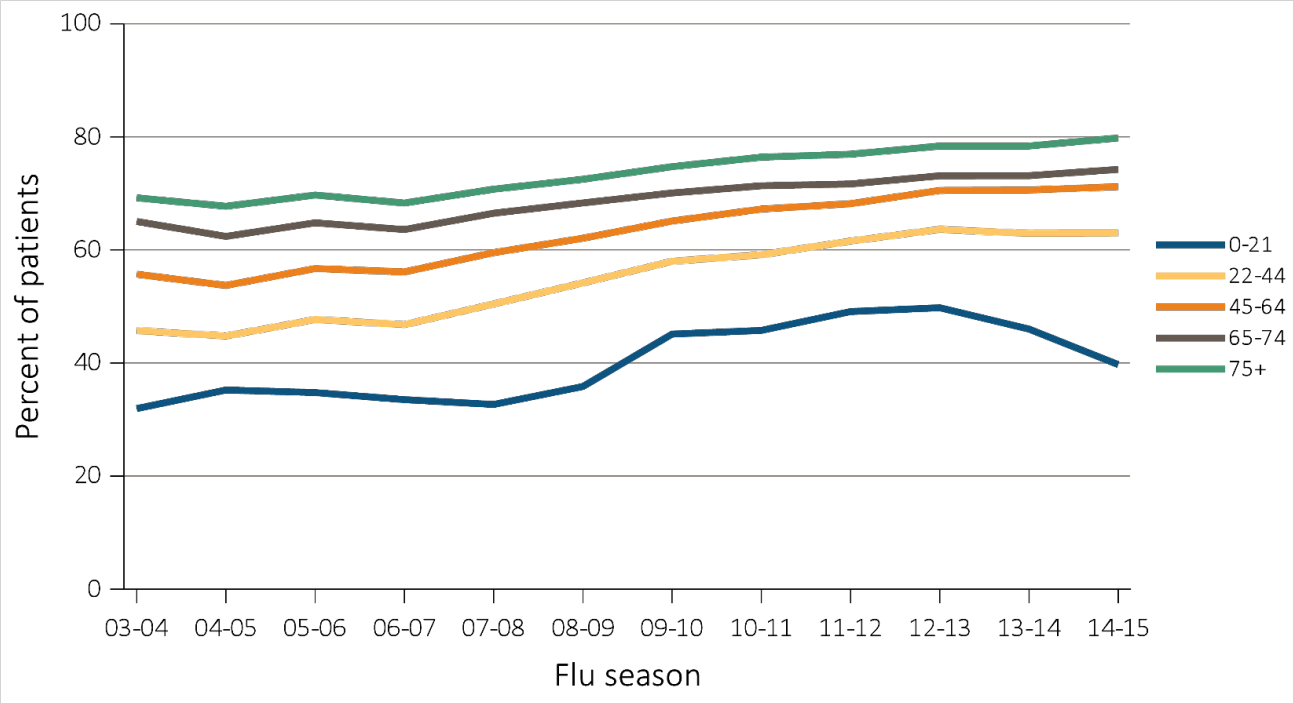
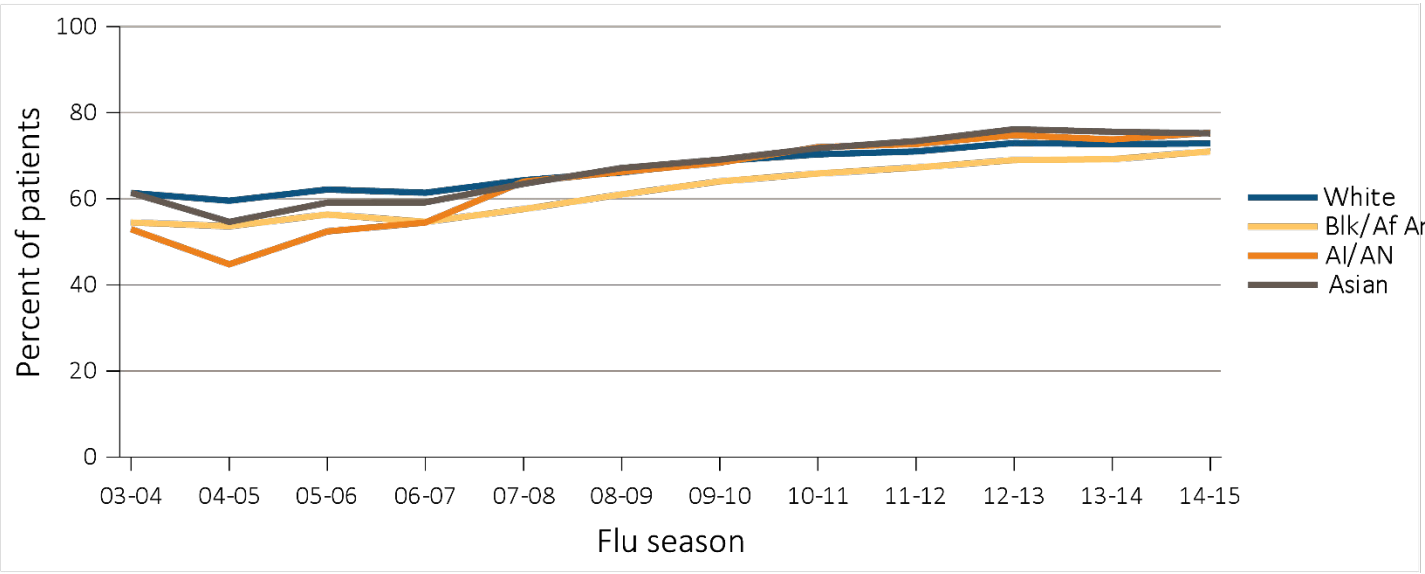


Figure 2.19 continued on next page.

vol 2 Figure 2.19 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), (a) overall, (b) by age, (c) by race (d) by ethnicity, and (e) by ESRD treatment modality, Medicare data, 2003-2015 *(continued)*

(c) Race



(d) Ethnicity

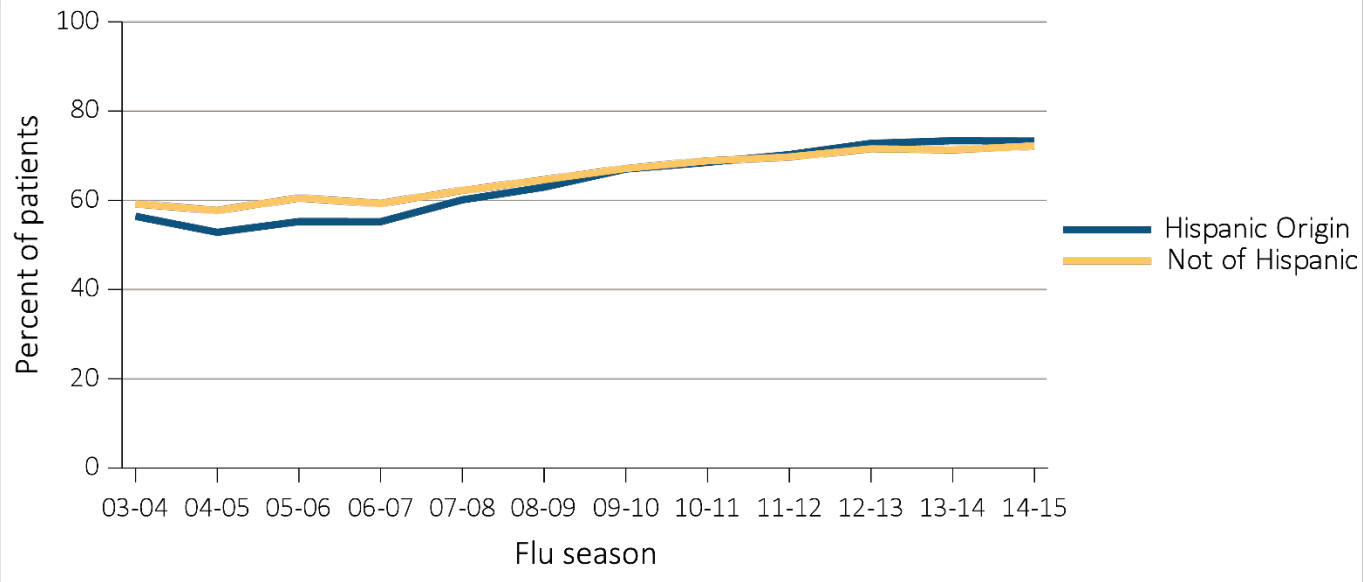
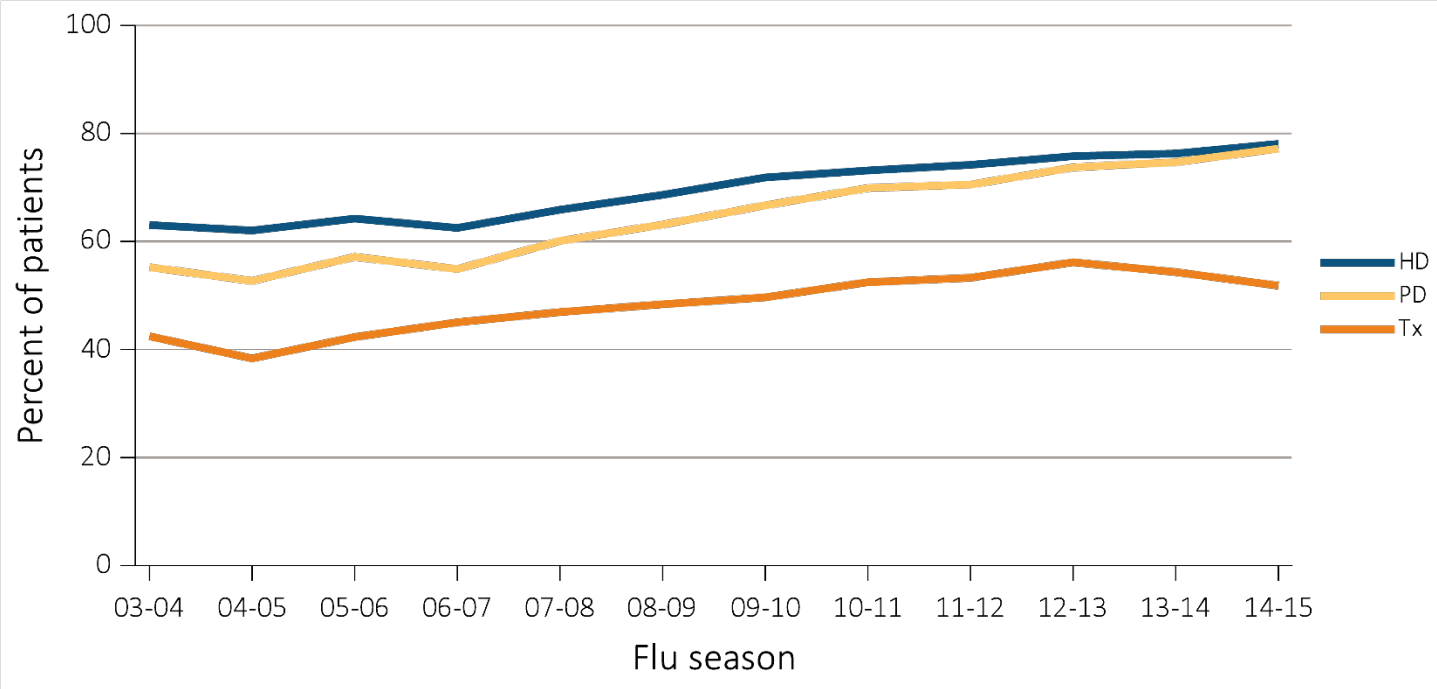


Figure 2.19 continued on next page.

vol 2 Figure 2.19 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), (a) overall, (b) by age, (c) by race (d) by ethnicity, and (e) by ESRD treatment modality, Medicare data, 2003-2015 *(continued)*

(e) Modality



Data Source: Special analyses, USRDS ESRD Database. ESRD patients initiating treatment for ESRD at least 90 days before seasonal period: August 1-April 30 for influenza. (c) Native Hawaiian/Pacific Islander, multiracial, and other/unknown races excluded due to small number of flu vaccination claims. Abbreviations: Af Am, African American; AI, American Indian; AN, Alaska Native; ESRD, end-stage renal disease; HD, hemodialysis; PD, peritoneal dialysis; Tx, transplant.

References

Fellstrom BC, Jardine AG, Schmieder RE, Holdaas H, Bannister K, et al. Rosuvastatin and cardiovascular events in patients undergoing hemodialysis. *N Engl J Med* 2009;360(14):1395-1407.

Kidney Disease: Improving Global Outcomes (KDIGO). *KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD).* http://kdigo.org/wp-content/uploads/2017/02/2017-KDIGO-CKD-MBD-GL-Update.pdf. Published July 2017. Accessed October 4, 2017.

National Committee for Quality Assurance. Comprehensive diabetes care. In *The State of Health Care Quality* 2013;October:51-55. https://www.ncqa.org/Portals/0/Newsroom/SOHC/2013/SOHC-web_version_report.pdf. Accessed October 10, 2015.

Wanner C, Krane V, Marz W, Olschewski M, Mann JFE, et al. Atorvastatin in patients with type 2 diabetes mellitus undergoing hemodialysis. *N Engl J Med* 2005;353(3):238-248.