Chapter 2: Clinical Indicators and Preventive Care

Anemia

- In May 2017, the majority (64.5%) of hemodialysis (HD) patients had hemoglobin (Hgb) levels from 10 to <12 g/dL, while 14.5% had Hgb ≥12 g/dL, 14.4% had Hgb from 9 to <10 g/dL, and 6.6% had Hgb <9 g/dL. The mean Hgb was 10.8 g/dL (Figure 2.1.b).
- In May 2017, the majority (56.1%) of peritoneal dialysis (PD) patients had Hgb levels from 10 to <12 g/dL, while 21.4% had Hgb ≥12 g/dL, 15.2% had Hgb from 9 to <10 g/dL, and 7.3% had Hgb <9 g/dL. The mean Hgb was 10.9 g/dL (Figure 2.1.b).
- As of 2016, three different erythropoiesis-stimulating agents (ESAs) were prescribed to dialysis patients in the United States (U.S.). December 2016 claims data indicated monthly use rates among HD patients on dialysis ≥90 days of 34.4% for epoetin (EPO) alfa, 17.9% for darbepoetin, and 24.4% for pegylated EPO (PEG-EPO) beta. 22.0% of HD patients were not using an ESA. Among PD patients, 31.2% were using EPO alfa, 13.0% darbepoetin, and 13.1% PEG-EPO, while 41.7% of PD patients were not using an ESA (Figures 2.2.d and 2.8.d.).
- For U.S. HD patients between 2015 and 2016, a small increase was seen in monthly percent intravenous (IV) iron use (60.0% to 61.8%), whereas mean monthly IV iron dose declined slightly (from 294.1 mg to 291.8 mg; Figure 2.4). Similarly, for PD patients a small increase was also seen in monthly percent IV iron use (25.3% to 26.5%) and decline in mean monthly IV iron dose (from 196.2 mg to 190.9 mg; Figure 2.10).
- Serum ferritin levels increased slightly in all dialysis patients from 2015 to 2017. As of May 2017, 30.4% and 25.5% of HD patients had serum ferritin levels of 801-1200 and >1200 ng/mL. Among PD patients, 22.4% and 17.2% had serum ferritin levels of 801-1200 and >1200 ng/mL (Figures 2.6 and 2.12).

Serum Albumin, Calcium, and Phosphorus

- In May 2017, 18.9% of HD and 44.3% of PD patients were hypoalbuminemic (<3.5 g/dL, Figure 2.1.d).
- In May 2017, 60.5% of HD and 57.5% of PD patients had serum calcium levels within the range of 8.4-9.5 mg/dL. About 1.3% of HD patients and 1.9% of PD patients had serum calcium levels greater than 10.2 mg/dL and 16.9% of HD patients and 23.1% of PD patients had serum calcium levels less than 8.4 mg/dL (Figures 2.14 and 2.15).
- In May 2017, 66.1% of HD patients and 71.6% of PD patients had serum phosphorus levels greater than 4.5 mg/dL (Figures 2.16 and 2.17).

Preventive Care

- In 2016, 83.4% of diabetic end-stage renal disease (ESRD) patients received at least one hemoglobin A1c (HbA1c) test, while 68.9% of patients received at least two HbA1c tests, 69.8% a lipid test, and 46.9% a dilated eye exam. However, only 28.8% of diabetic ESRD patients received comprehensive diabetes monitoring that includes at least two HbA1c tests and one of each of a lipid exam and a diabetic eye exam. This was a decline from 36.4% comprehensive monitoring in 2010, although in 2010, one HbA1c exam was accepted as the clinical standard (Figure 2.18).
- In the 2015-2016 flu season, 71.3% of patients received an influenza vaccination. Although this rate has been stable over the last two years, the percent vaccinated has increased from 59.3% a decade earlier (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.

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. Downloadable Microsoft Excel and PowerPoint files containing the data and graphics for this chapter's figures and tables are available on the *USRDS website*.

See the section addressing *Chapter 2* in the *ESRD Analytical Methods* chapter for an explanation of the analytical methods used to generate the study cohorts, figures, and tables in this chapter. Limits were applied regarding the maximum allowable IV iron and ESA doses shown in this chapter as follows: (1) for erythropoetin alfa (EPO) dose calculations - patients were excluded for a given month if their monthly average EPO dose was either <250 units or >400,000 units per week; there were no darbepoetin or PEG-EPO doses that exceeded the EPO dose maximum after applying conversion factors often used for darbepoetin and PEG-EPO in comparison to EPO; (2) for IV iron dose calculations, analysis was restricted to patients receiving 7 to 18 IV administrations in a month, and in the case of iron sucrose and ferrous gluconate received 50-1800 mg or 12.5-1800 mg, respectively.

Clinical Indicators

In Figure 2.1, we present CROWNWeb data from May 2017 for a selection of clinical indicators relating to dialysis adequacy, achieved Hgb level, serum calcium, and serum albumin. Figure 2.1.a shows that achievement of dialysis adequacy targets for HD was nearly universal, with 97.1% 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 89.1% (Figure 2.1.a). These targets are part of the QIP, and were set based on clinical trial and observational evidence demonstrating associations with mortality.

Views on anemia treatment with ESAs have evolved in recent years towards maintaining hemoglobin levels at lower target ranges than previously, due, in part, to safety concerns that emerged from controlled CKD clinical trials related to anemia correction. In these trials, greater risks of death, serious adverse cardiovascular reactions, and stroke were observed for study participants 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 (*https://www.fda.gov/Drugs/DrugSafety/ucm259639.htm*). In addition, current guidelines do not specify an appropriate lower limit, which likely has also contributed to generally lower Hgb levels among dialysis patients during the past decade. Moreover, a financial disincentive for prescribing higher ESA doses came about in 2011, when CMS implemented the End-Stage Renal Disease Prospective Payment System (PPS), which bundled injectable medications such as ESAs into the payment received by HD facilities for providing dialysis for ESRD patients.

CROWNWeb includes data from both Medicare and non-Medicare insured patients, and thus presents a more representative view of Hgb levels for the

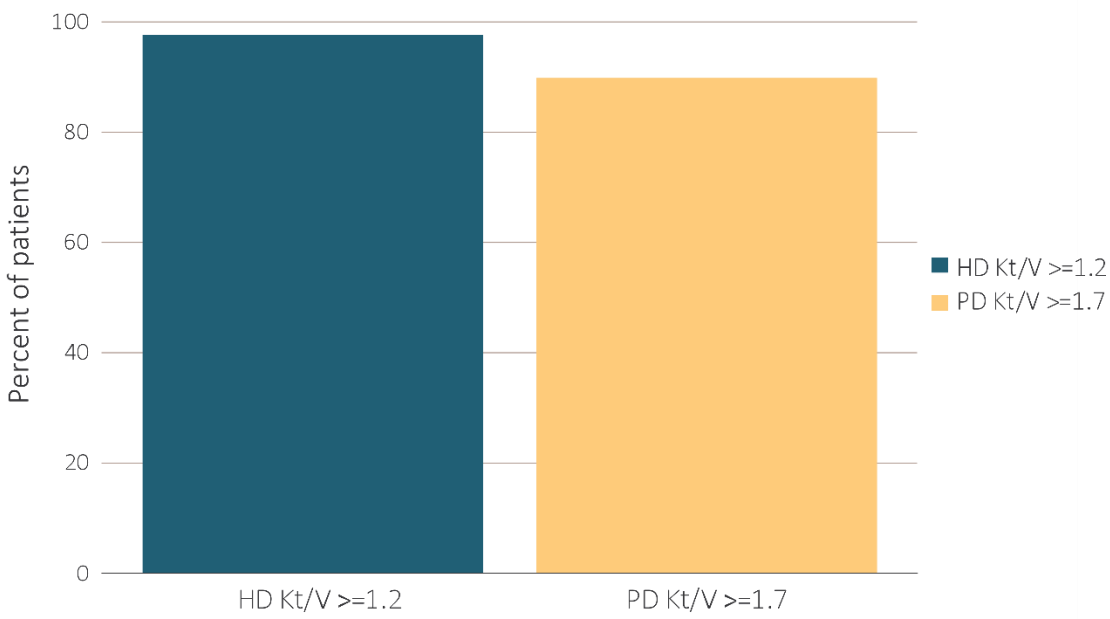
dialysis population than was previously possible through analyses based only upon claims data (Figure 2.1.b). In May 2017, the majority (64.5%) of both ESA-treated and non-ESA treated HD patients had Hgb levels in the range of 10 to 12 g/dL, with 14.5% having Hgb ≥12 g/dL. The pattern was similar with PD patients, though a somewhat higher percentage (21.4%) had Hgb ≥12 g/dL. Later in this chapter, we utilize Medicare claims through 2016 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 2017 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 ESRD QIP. The rationale for this quality measure is to avoid elevated levels of calcium given the associations with vascular calcifications and cardiovascular events. For both modalities, the percent of patients with hypercalcemia has declined compared to May 2016, with 0.7% and 1.0% of HD and PD patients having a 3-month mean serum calcium >10.2 mg/dL as of May 2017. Later in the chapter, we present additional CROWNWeb data on trends in both serum calcium and phosphorus levels, which have also been associated with cardiovascular mortality.

Figure 2.1.d presents CROWNWeb data as of May 2017 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 its strong association with mortality, we include national information on albumin levels. As of May 2017, 18.9% of HD and 44.3% 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 due in part to peritoneal losses of protein during peritoneal dialysis.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis and peritoneal dialysis patients in CROWNWeb data, May 2017: (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

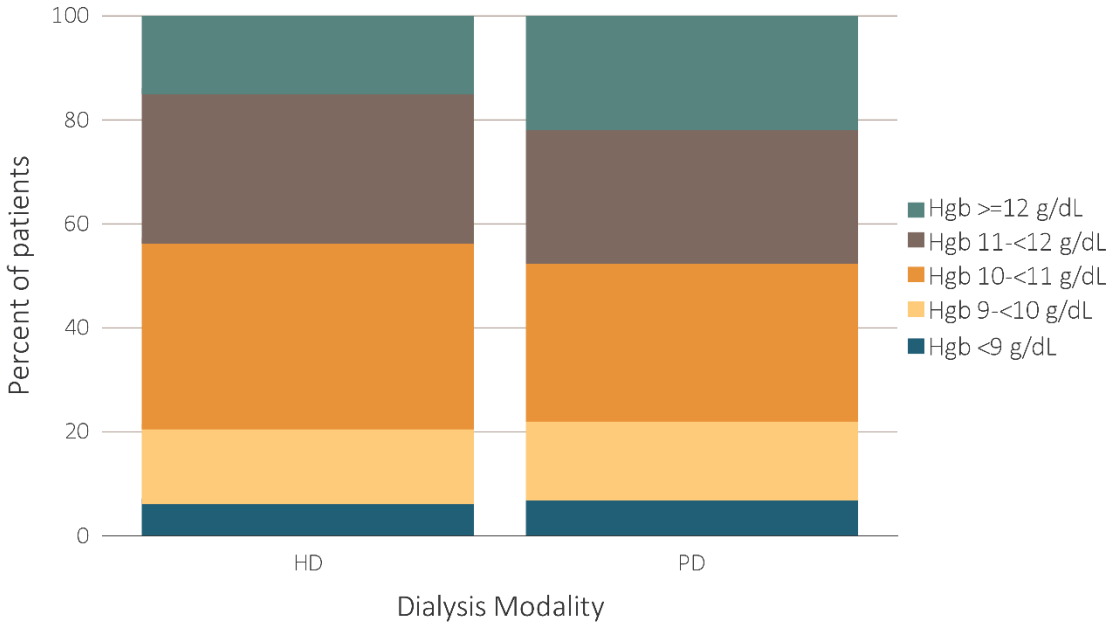
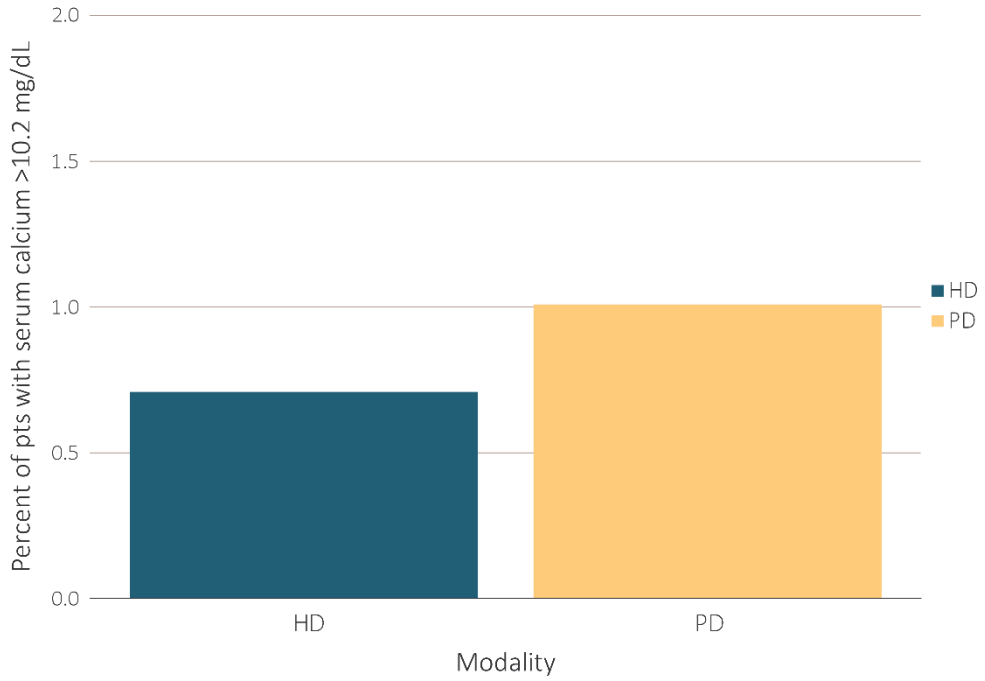


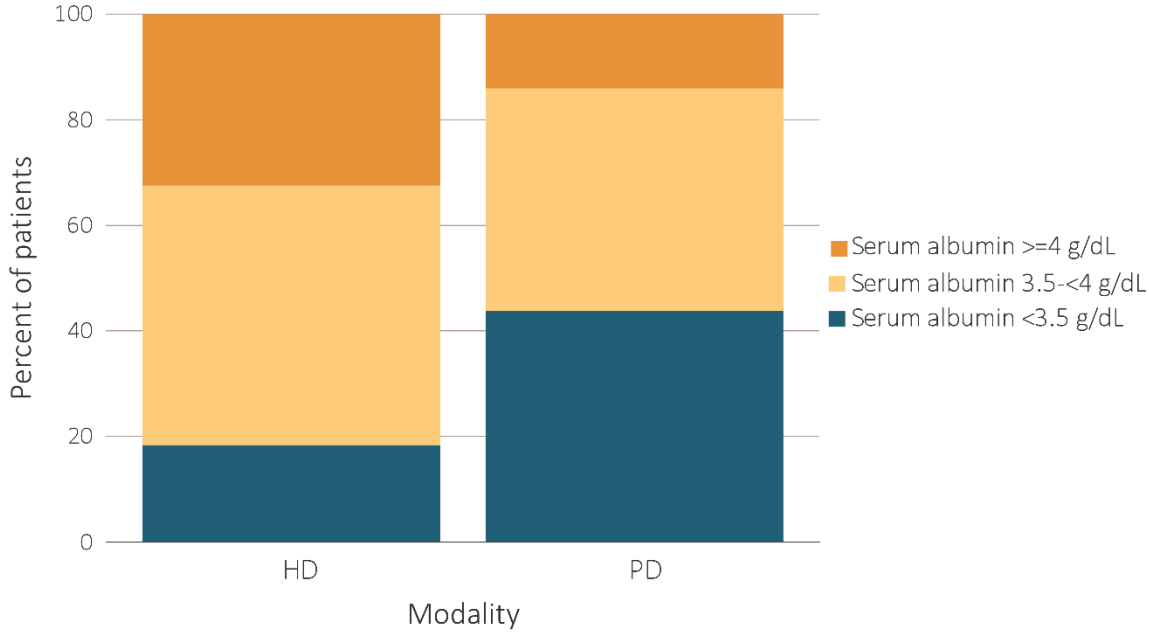
Figure 2.1 continued on next page.

vol 2 Figure 2.1 ESRD clinical indicator levels among prevalent hemodialysis and peritoneal dialysis patients in CROWNWeb data, May 2017: (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 2017, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to May 1, 2017, and who were alive through May 31, 2017; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, who were ≥18 years old as of May 1, 2017, and who were alive through May 31, 2017; (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, who were ≥18 years old as of May 1, 2017, and who were alive through May 31, 2017; and (d) dialysis patients initiating treatment for ESRD at least 90 days prior to May 1, 2017, who were ≥18 years old as of May 1, 2017, and who were alive through May 31, 2017. 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, type, and dose, IV iron use and dose, levels of iron store markers, and red blood cell transfusion rates. We report analyses of CMS claims data by dialysis modality through 2016. Starting in 2011, a striking practice change is seen in anemia management of U.S. dialysis patients manifested by a large decline in hemoglobin levels, tightly coupled with a substantial decline in ESA use, and administered ESA and IV iron doses. This practice change was largely in response to the January 2011 implementation of the CMS ESRD Prospective Payment System (PPS) - which provided a financial disincentive for administration of injectable drugs - and the FDA's communication in June 2011 recommending more conservative ESA use and dosing (*https://www.fda.gov/Drugs/DrugSafety/ucm259639.htm*). In addition, the types of ESAs available for treating anemia have increased over time, now including agents with substantially longer half-lives compared to the shorter acting epoetin alfa introduced in 1989. In this regard, darbepoetin and pegylated erythropoietin beta (PEG-EPO) use began in 2005 and 2015 in the United States, respectively, with a little more than half of all ESA use now occurring via these two longer acting ESAs in 2016. There are a number of different considerations made by physicians and dialysis units in deciding which ESA type to prescribe for their patients, and doses of ESAs and IV iron to prescribe (e.g., most appropriate drug for a particular patient based upon a variety of patient-level considerations, financial costs, how drug administration relates to staffing time/expertise and how it is distributed and applied during dialysis shifts, etc.).

Changes in availability of certain types of anemia management-related data have occurred over time. Monthly mean IV iron doses are provided starting in 2005. 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 has allowed for comparisons of Hgb values for ESA-treated patients, non-ESA treated patients, and all patients combined starting in April 2012.

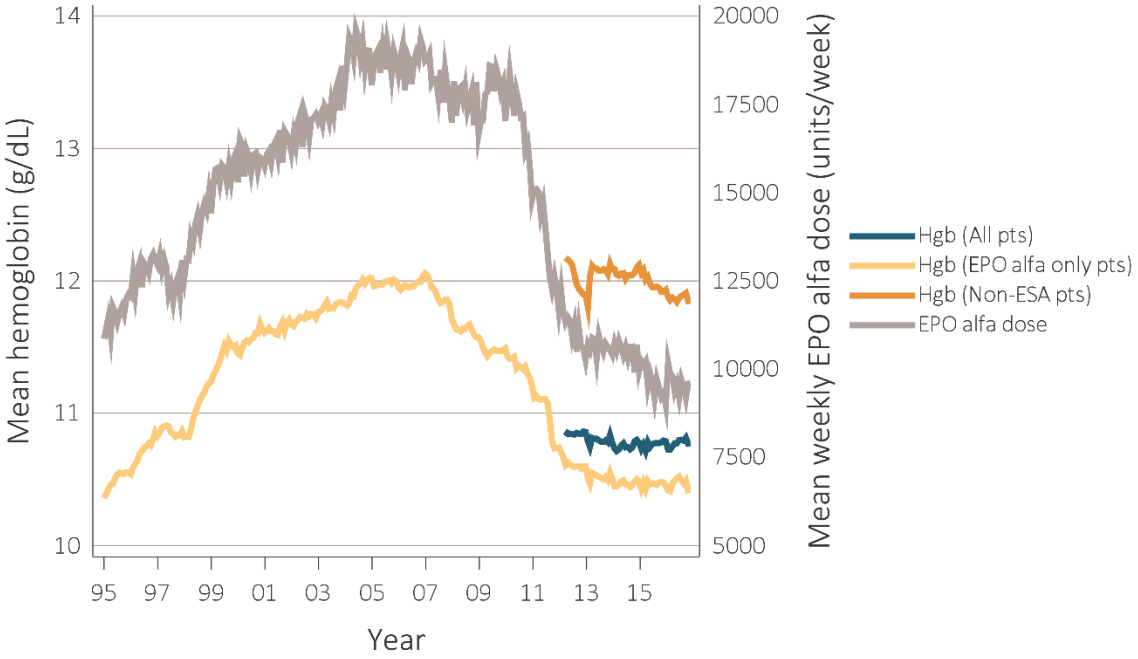
Hgb Levels, ESA Use and Dose by ESA type, in Hemodialysis Patients

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 levels 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 10.4 g/dL in 2016. Mean monthly Hgb values in 2016 were 10.8 g/dL for all HD patients on dialysis ≥90 days and 11.9 g/dL for non-ESA treated patients. In 2016, mean monthly Hgb levels were quite similar across the types of ESA used, with mean Hgb levels of 10.4, 10.4 and 10.5 g/dL seen for patients prescribed EPO alfa, darbepoetin, and PEG-EPO, respectively, in December 2016.

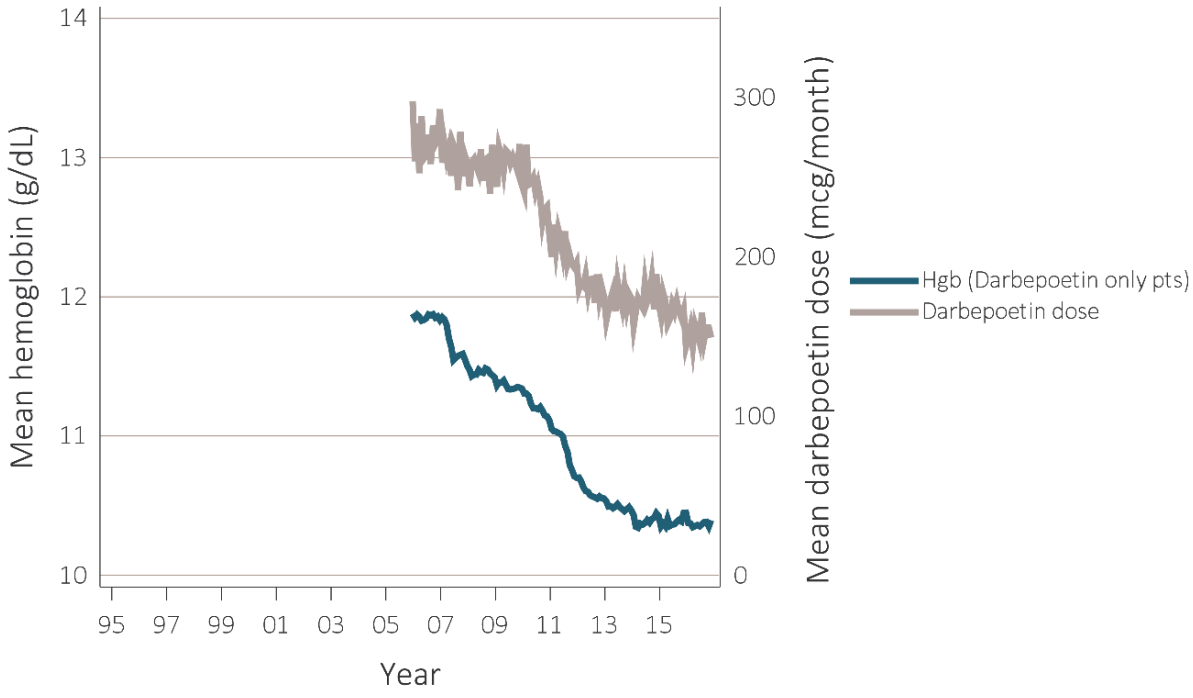
In 2016, 78%-80% of HD patients on dialysis for ≥90 days had a claim for ESA use during any single month (Figure 2.2.d). From December 2014 to December 2015, there was a large shift in the type of ESA prescribed to Medicare patients. In December 2014, 77.4% and 5.0% of patients were prescribed EPO alfa and darbepoetin, but by December 2015, 42.6%, 14.0%, and 20.5% were prescribed EPO alfa, darbepoetin, and PEG-EPO. In 2016, the shift away from EPO alfa slowed a bit. The percentages became 34.4%, 17.9%, and 24.4% for EPO alfa, darbepoetin, and PEG-EPO, respectively, in 2016. Between December 2007 and December 2016, mean weekly EPO alfa doses (averaged over a month) declined by more than 50% in HD patients to 9616.1 units/week by December 2016. The mean monthly darbepoetin and PEG-EPO doses that were prescribed in December 2016 were 149.4 mcg/month and 158.3 mcg/month, respectively. The mean weekly EPO alfa dose (averaged monthly) declined slightly from 2015 to 2016.

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 monthly ESA use, Medicare claims, 1995-2016

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



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



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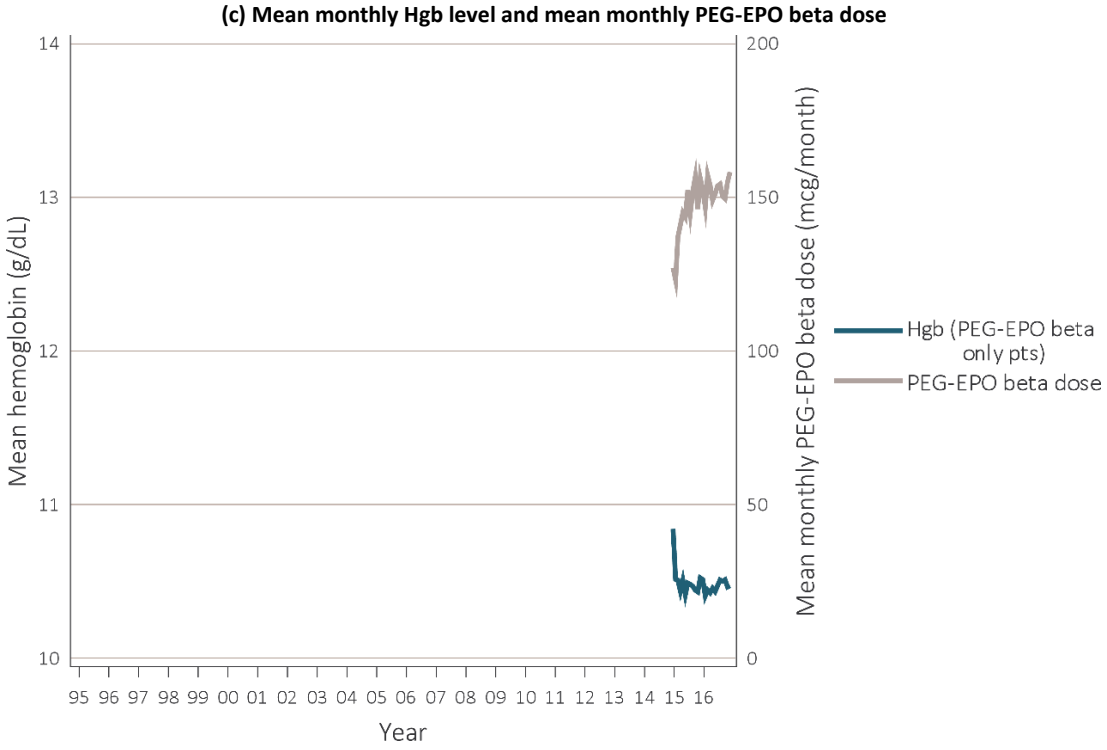
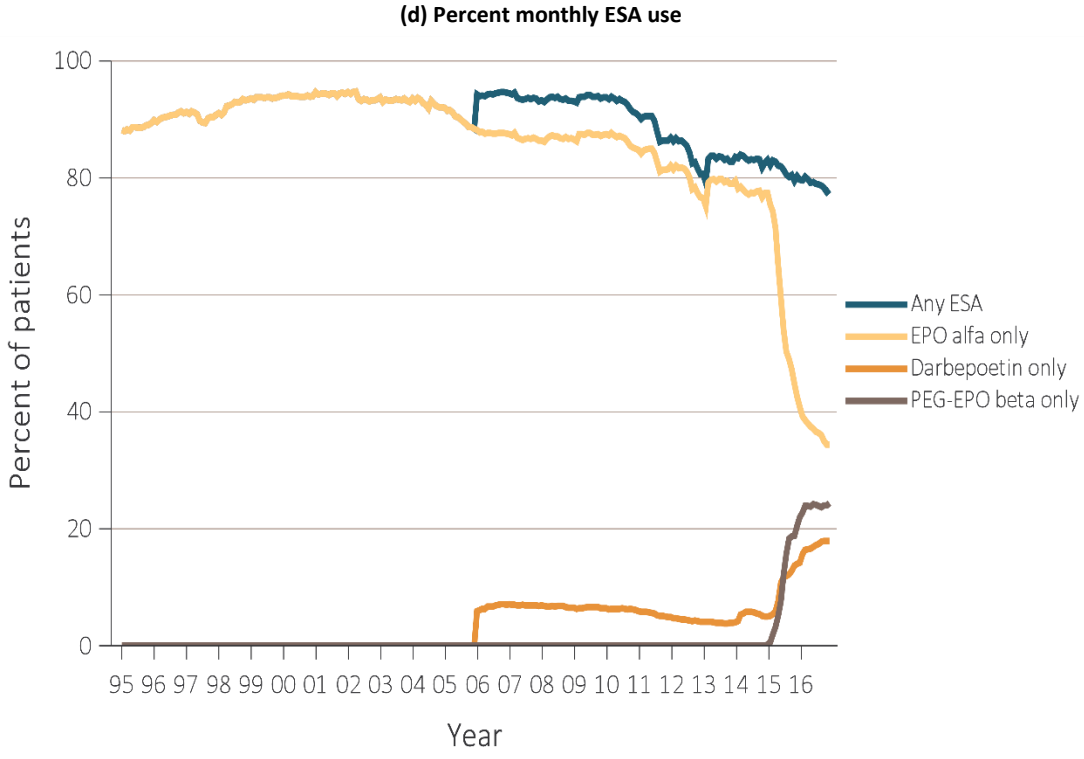
vol 2 Figure 2.2 Anemia measures among adult hemodialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb level and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PEG-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016 (continued)

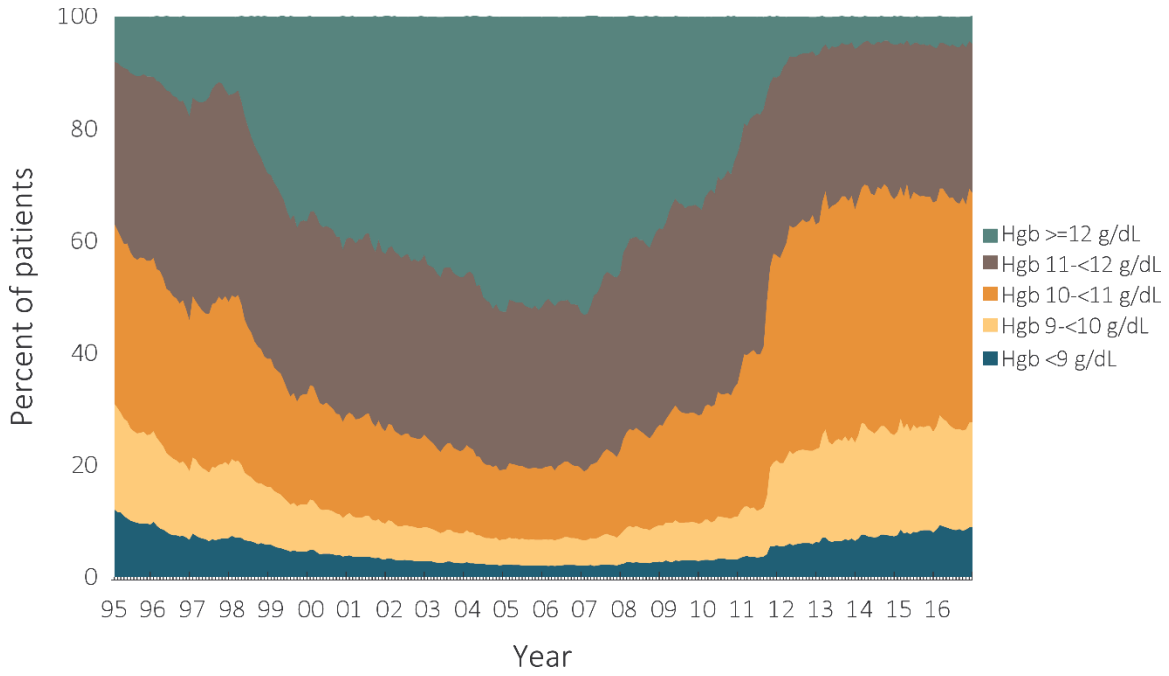




Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a)EPO alfa (b) darbepoetin (c) PEG-EPO beta patients on dialysis ≥ 90 days (1995-2016) or (a) mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2016 only) who, within the given month had a Hgb claim (only 1st reported Hgb values 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 within 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; ESRD, end-stage renal disease; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2016, a large shift occurred in the percentage of ESA-treated adult HD patients who had the highest versus lowest levels of Hgb (Figure 2.3). Among ESA-treated patients on dialysis ≥90 days, the percentage with Hgb between 9 to 10 g/dL increased from 5.0% in 2007 to 18.5% in 2016, while the percentage with Hgb ≥12 g/dL declined nearly 10-fold from 48.5% in 2007 to 5.1% in 2016. For the group of all HD patients on dialysis ≥90 days in December 2016, 8.9% had Hgb <9 g/dL, 18.7% had Hgb of 9 to <10 g/dL, 40.9% had Hgb between 10-<11 g/dL, 26.6% had Hgb between 11-<12 g/dL, and 5.0% 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, 1995-2016

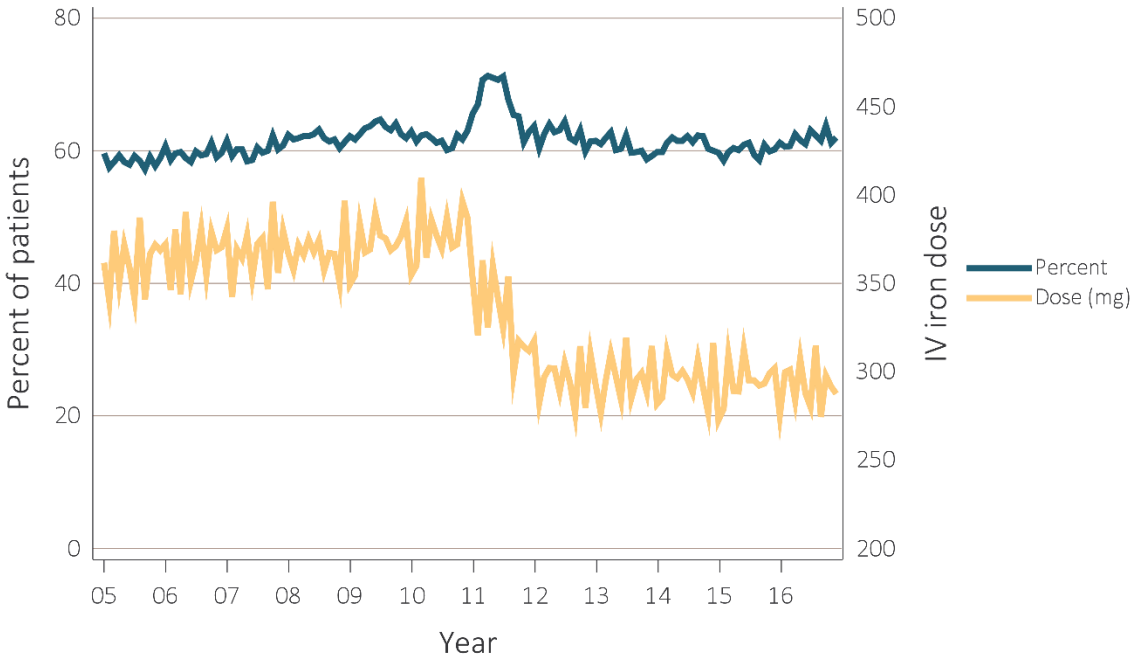


Data Source: Special analyses, USRDS ESRD Database. Distribution of monthly Hgb levels among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESRD, end-stage renal disease; ESA, erythropoiesis-stimulating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

Intravenous (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 2016 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 62% by December 2016, similar to rates prior to the start of the bundled PPS in 2011. 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, and since have gradually declined further to 292 mg in 2016. Thus, since 2011, both IV iron use and the average monthly IV iron dose have declined among HD patients in the United States.

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, 2005-2016

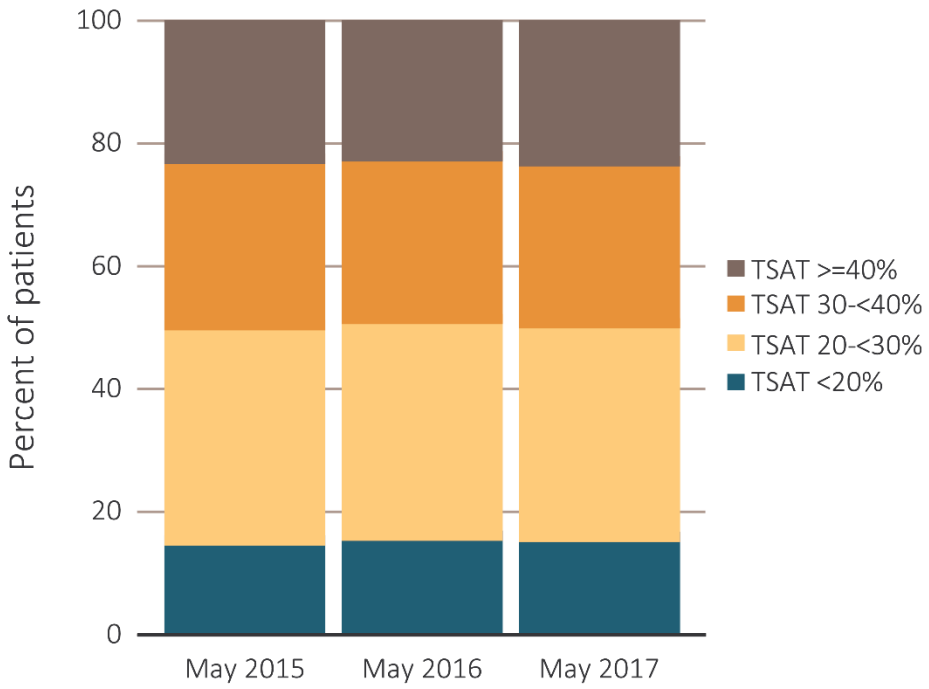


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients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

U.S. dialysis units now report iron store measures, transferrin saturation (TSAT), and serum ferritin as part of CROWNWeb data collection. Reporting of these measures to CROWNWeb has increased over time.

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 2015-2017. Averaged across this period, 15.8% of patients had a TSAT <20%, with 35.1%, 26.7%, and 22.5% 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 15.3% to 15.9% from May 2015-2017, and is seen to be modestly lower with increasing age and higher among Whites compared to other HD patients in 2017 (Table 2.1). During 2015-2017, on average 4.9% of patients had serum ferritin ≤200 ng/mL, with 16.0%, 24.8%, 31.0%, and 23.3% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. In 2017, serum ferritin levels were markedly higher among patients of older age with a nearly 2-fold higher prevalence of ferritin >1200 ng/mL among patients ≥75 years old (29.2%) versus patients 0-21 years old (14.7%). Furthermore, 2017 serum ferritin levels were modestly higher among females compared to males, whereas patients with cystic kidney disease as the primary cause of ESRD had somewhat lower serum ferritin level (Table 2.2).

vol 2 Figure 2.5 Distribution of TSAT levels in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2015, 2016, and 2017



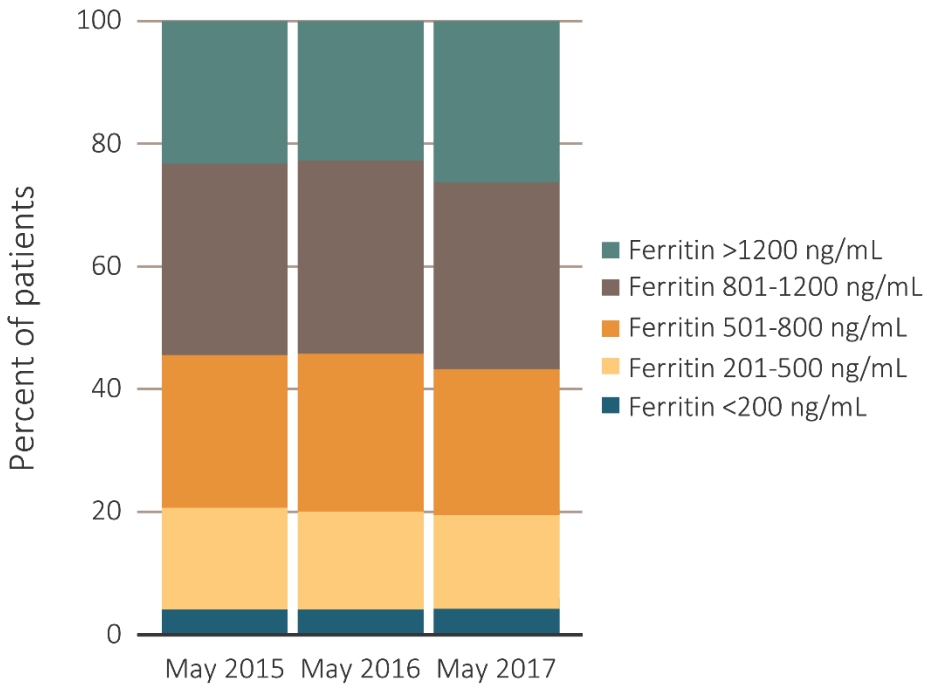
Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; TSAT, transferrin saturation.

vol 2 Table 2.1 TSAT by age, sex, race, and primary ESRD cause in hemodialysis patients, May 2017

	N	TSAT <20%	TSAT 20-<30%	TSAT 30-<40%	TSAT≥40%
Overall	**441,443**	**15.9%**	**34.8%**	**26.4%**	**22.8%**
Age					
0-21	1,043	21.5	25.2	23.3	30.0
22-44	50,498	16.8	34.5	25.4	23.4
45-64	183,368	16.1	35.2	26.2	22.4
65-74	114,918	15.5	34.6	27.1	22.8
75+	91,616	15.3	34.7	26.7	23.4
Sex					
Male	252,263	15.8	34.6	27.1	22.5
Female	189,163	16.0	35.1	25.6	23.3
Race					
White	250,955	16.3	34.4	26.4	22.8
Black/African American	159,310	15.3	35.7	26.6	22.4
American Indian or Alaska Native	5,379	15.7	33.5	26.0	24.9
Asian	17,991	14.6	33.5	26.2	25.8
Primary cause of ESRD					
Diabetes	206,682	15.9	35.5	26.5	22.0
Hypertension	130,743	15.5	34.5	26.6	23.4
Glomerulonephritis	45,037	16.0	33.9	26.3	23.8
Cystic Kidney	11,161	17.3	35.7	26.9	20.1
Other/Unknown	45,199	16.1	33.3	25.7	24.9

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March through May of 2017. 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, 2017 and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; TSAT, transferrin saturation.

vol 2 Figure 2.6 Distribution of the most recent serum ferritin level taken between March and May in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. 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. Figure includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

vol 2 Table 2.2 Serum ferritin by age, sex, race, and primary ESRD cause in hemodialysis patients, May 2017

	N	Ferritin <200 ng/mL	Ferritin 201-500 ng/mL	Ferritin 501-800 ng/mL	Ferritin 801-1200 ng/mL	Ferritin >1200 ng/mL
Overall	**436,264**	**5.0%**	**15.3%**	**23.8%**	**30.4%**	**25.5%**
Age						
0-21	1,033	9.2	29.3	24.3	22.5	14.7
22-44	49,927	6.8	18.9	24.7	28.0	21.5
45-64	181,274	5.7	16.3	24.2	29.8	24.2
65-74	113,489	4.3	14.3	23.4	31.2	26.7
75+	90,541	3.3	12.7	22.9	31.9	29.2
Sex						
Male	249,218	5.9	16.9	24.6	29.6	23.0
Female	187,029	3.8	13.3	22.7	31.4	28.9
Race						
White	247,758	5.3	16.3	24.6	30.3	23.5
Black/African American	157,733	4.6	14.0	22.3	30.2	28.9
American Indian or Alaska Native	5,363	5.9	17.5	25.8	29.6	21.2
Asian	17,813	3.6	13.4	25.3	31.8	25.9
Primary cause of ESRD						
Diabetes	203,988	4.4	15.6	24.5	30.8	24.7
Hypertension	129,318	4.7	14.7	23.1	30.5	27.0
Glomerulonephritis	44,653	5.9	14.9	23.1	29.6	26.5
Cystic Kidney	11,092	12.5	18.4	22.0	27.5	19.6
Other/Unknown	44,641	5.3	15.6	23.7	29.6	25.9

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May 2017. 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, 2017, and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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 2012 through 2016, is shown in Figure 2.7.a. The results represent the 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. The frequency of red blood cell transfusions decreased during 2012 to 2016.

In 2012, 23.9% of HD patients received ≥1 red blood cell transfusions. This decreased to 21.3% of patients in 2014 and further to 16.6% in 2016. Across this five-year period, typically 10.3%-13.8% of patients received one red blood cell transfusion per year, 3.4%-5.4% received two, 1.3%-2.1% received three, and 1.6%-2.6% received four or more red blood cell transfusions per year.

Trends from 2011-2016 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 3.3% in the first quarter of 2014 to 2.4% by the third quarter of 2016. 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 2016, an average of 2.3% of White patients had one or more red blood cell transfusions in a month compared to 1.6% of African American/Black patients and 2.5% of those of Other or Unknown race. Note that since these differences were small, only the overall trend 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 claim 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 HD session, 2012-2016

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

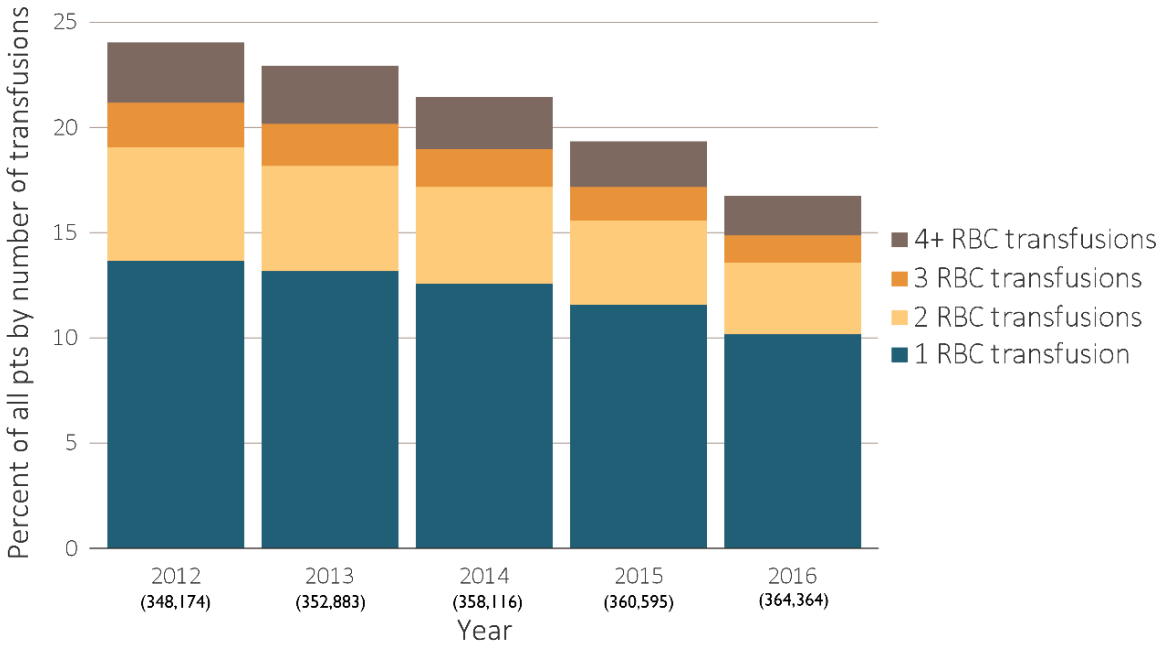
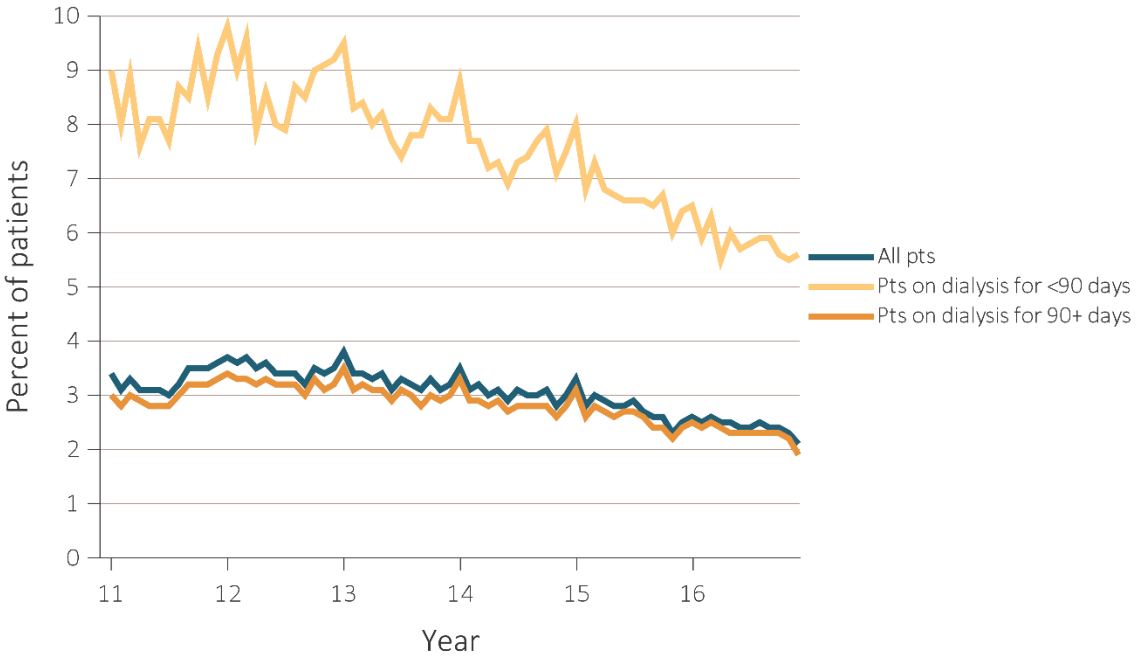


Figure 2.7 continued on next page.

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 claim 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 HD session, 2012-2016 (continued)

(b) Percent of all 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. (a) The percent of hemodialysis patients ≥18 years with total number of red blood cell transfusion claims in a given year among dialysis patients having a claim for at least one hemodialysis session during the year. (b) 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. Abbreviations: ESRD, end-stage renal disease; RBC, red blood cell; Pts, patients.

Hemoglobin (Hgb) Levels, and ESA Use and Dose, by ESA type, in Peritoneal Dialysis Patients

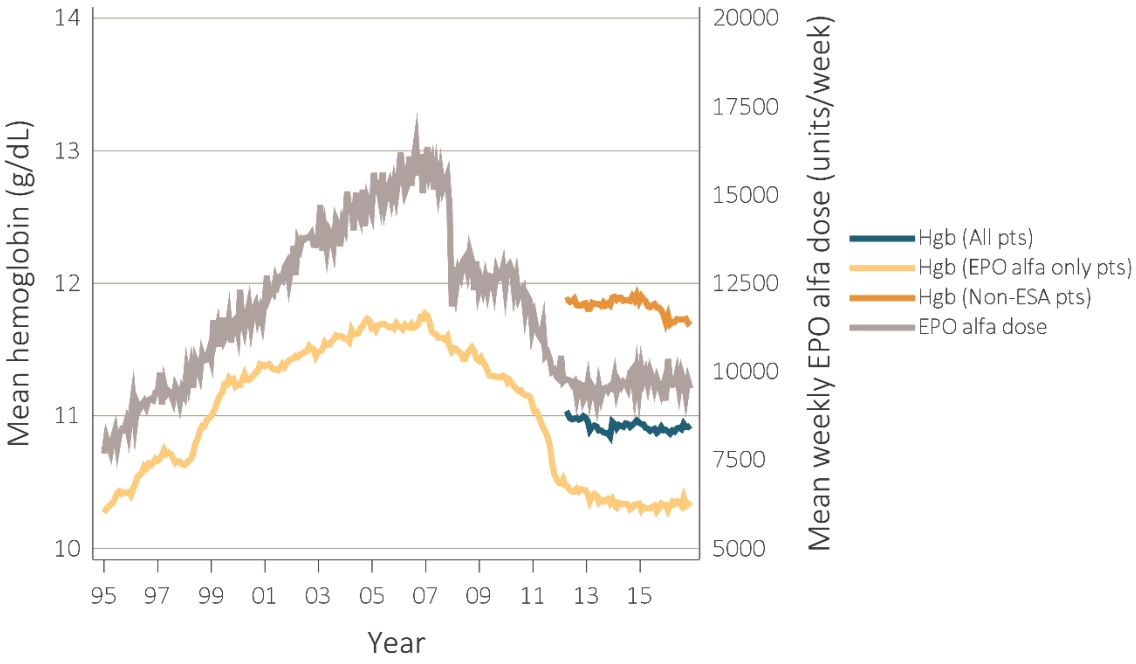
Claims data indicate that mean Hgb levels have declined substantially in ESA-treated PD patients since peaking near 11.8 g/dL in January 2007 (Figure 2.8.a). During 2011, patients' mean Hgb levels declined by 0.6 g/dL, from 11.1 g/dL to 10.5 g/dL. This was a larger decline, with a lower achieved mean Hgb level than that seen among ESA-treated hemodialysis patients overall during 2011. Since then, levels have continued to decline to a mean monthly Hgb of 10.3 g/dL in 2016 among ESA-treated PD patients on dialysis ≥90 days. In contrast, in 2016, mean monthly Hgb values of 10.9 g/dL were seen for all PD patients on dialysis ≥90 days, and 11.7 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 2016, at 58%-60% of patients (Figure 2.8.d). From December 2014 to December 2016, there was a large shift in the type of ESA prescribed to PD patients, with 57.1% and 4.5% prescribed EPO-alfa and darbepoetin in December 2014, compared to 31.2%, 13.02%, and 13.1% prescribed EPO alfa, darbeopoetin, and PEG-EPO beta in December 2016.

Among PD patients on dialysis ≥90 days in December 2016, the mean weekly EPO alfa dose was 9525.9 units/week, which was similar to that prescribed in 2014 and 2015. For the other two ESA types, the mean monthly darbepoetin and PEG-EPO doses that were prescribed in December 2016 were 152.6 mcg/month and 152.2 mcg/month, respectively. 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, (c) mean monthly Hgb level and mean monthly PED-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016

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



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

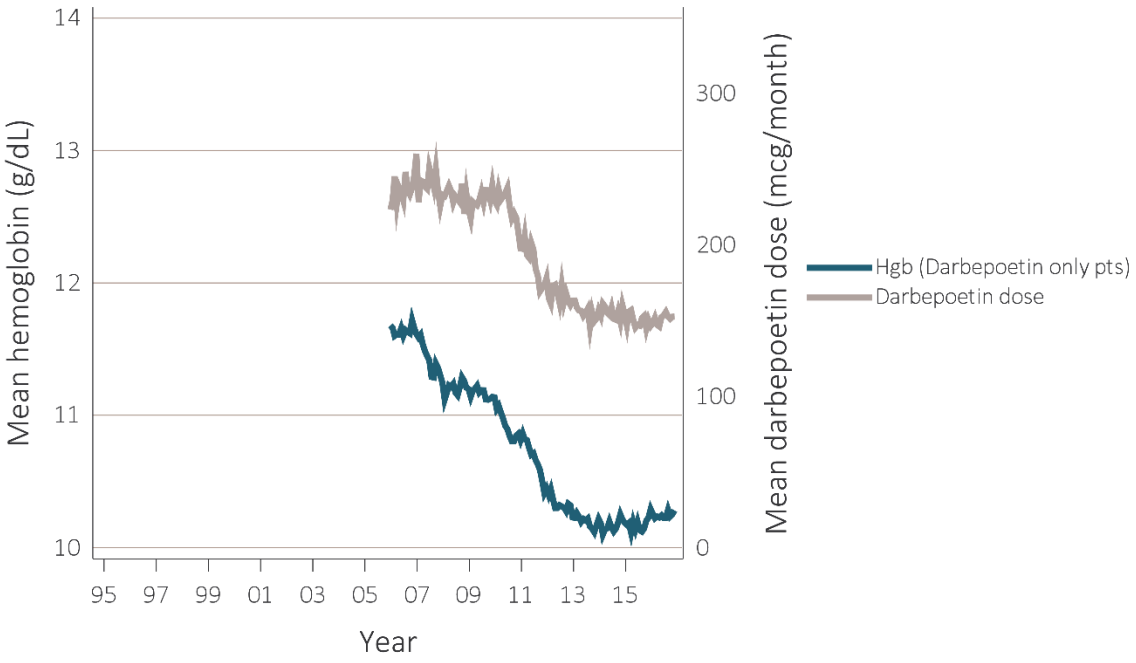


Figure 2.8 continued on next page.

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, (c) mean monthly Hgb level and mean monthly PED-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016 (continued)

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

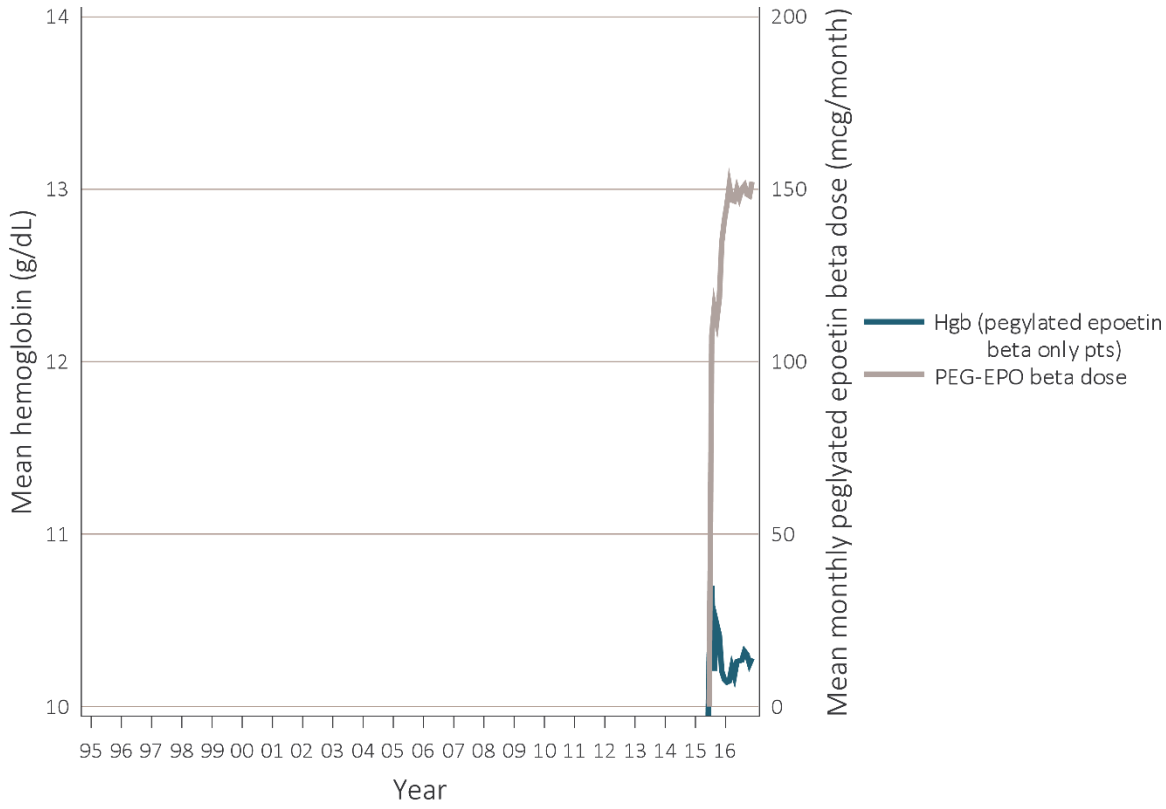
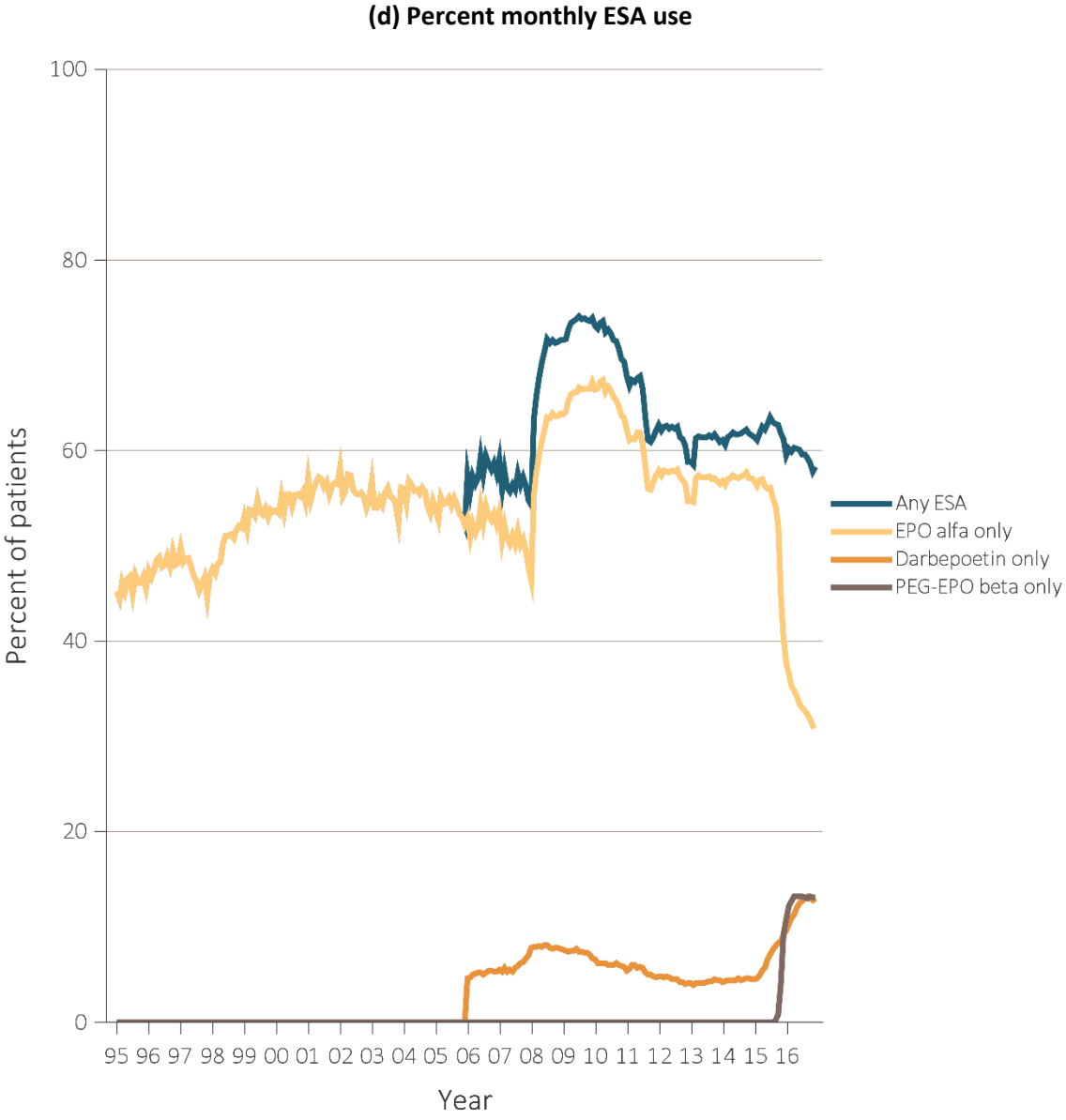


Figure 2.8 continued on next page.

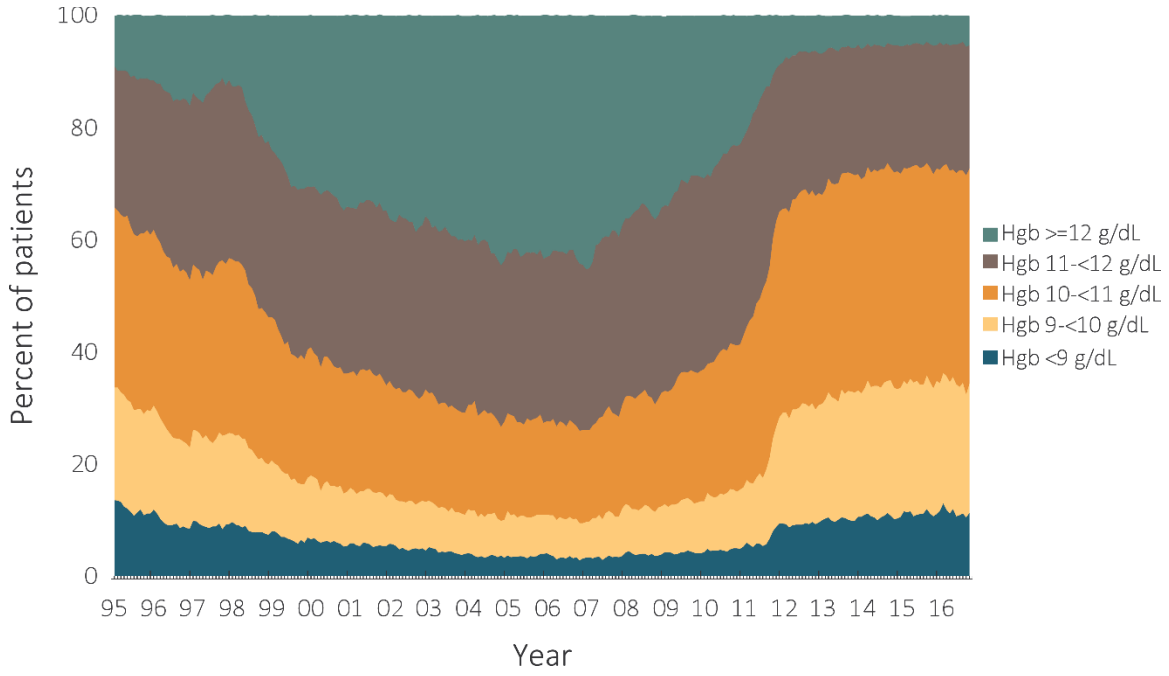
vol 2 Figure 2.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥90 days: (a) mean monthly Hgb level and mean weekly EPO alfa dose (averaged over a month), (b) mean monthly Hgb and mean monthly darbepoetin dose, (c) mean monthly Hgb level and mean monthly PED-EPO beta dose, and (d) percent monthly ESA use, Medicare claims, 1995-2016 (continued)



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among (a) EPO alfa-, (b) darbepoetin, (c)PEG-EPO beta on dialysis ≥ 90 days (1995-2016) or (a) mean monthly Hgb level among all adult peritoneal dialysis patients (April 2012 to December 2016 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 2.8.a) or monthly (darbepoetin, Figure 2.8.b & PEG-EPO beta, Figure 2.8.C) 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 and PEG-EPO beta doses 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 (EPO alfa, Darbepoetin, or PEG-EPO beta) in all peritoneal dialysis patients who were ≥ 18 years and on dialysis ≥ 90 days. Abbreviations: EPO alfa, erythropoietin alfa; ESRD, end-stage renal disease; PEG-EPO beta, pegylated erythropoetin beta; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2014, a large shift occurred in the percentage of PD patients in the highest versus lowest Hgb concentration categories, but has remained relatively stable from 2014-2016 (Figure 2.9). Among ESA-treated adult patients on PD ≥90 days, the percentage with Hgb between 9 and 10 g/dL increased from 7.4% in 2007 to 23.1% in 2016, while the percentage with Hgb ≥12 g/dL declined from 37.5% in December 2007 to 5.5% in December 2016. Among all PD patients on dialysis ≥90 days in December 2016, 10.8% had Hgb <9 g/dL, 22.3% had Hgb of 9 to <10 g/dL, 38.6% had Hgb between 10-<11 g/dL, 22.9% had Hgb between 11-<12 g/dL, and 5.5% 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, 1995-2016

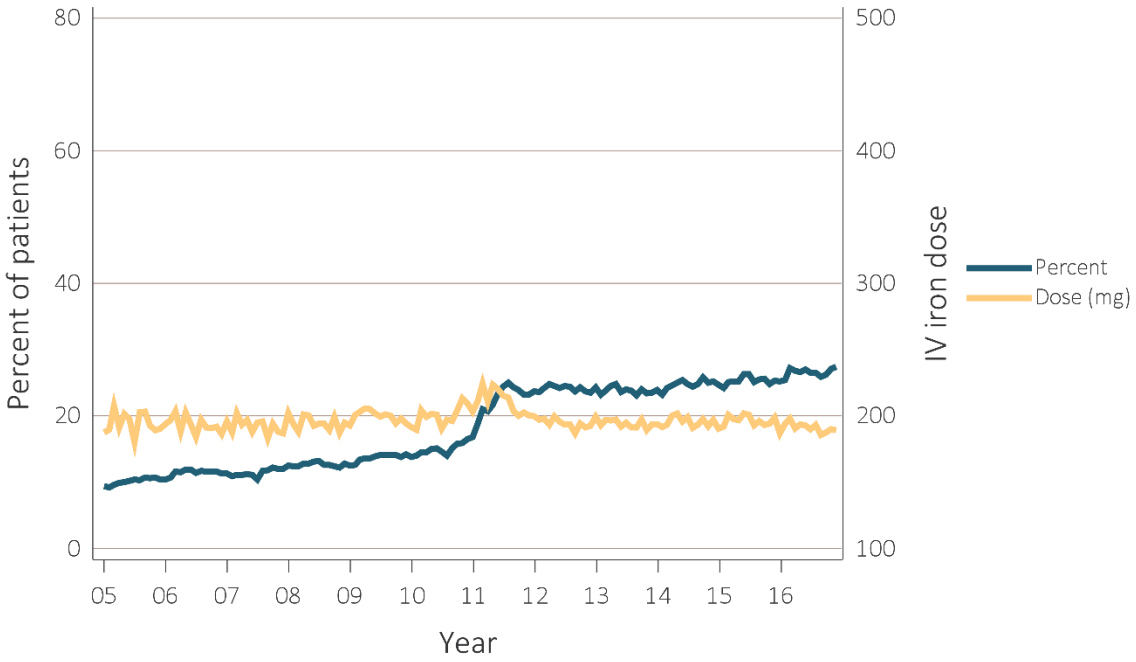


Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥90 days and ≥18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents;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

Intravenous (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 2016 (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 2016, IV iron use among PD patients on dialysis ≥90 days remained higher, at 26.9%. 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 from 195 mg in 2012 to 191 mg in 2016. Thus, since 2011, IV iron use in the United States has increased slightly among PD patients, while the average monthly IV iron dose has declined among PD patients prescribed IV iron.

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, 2005-2016

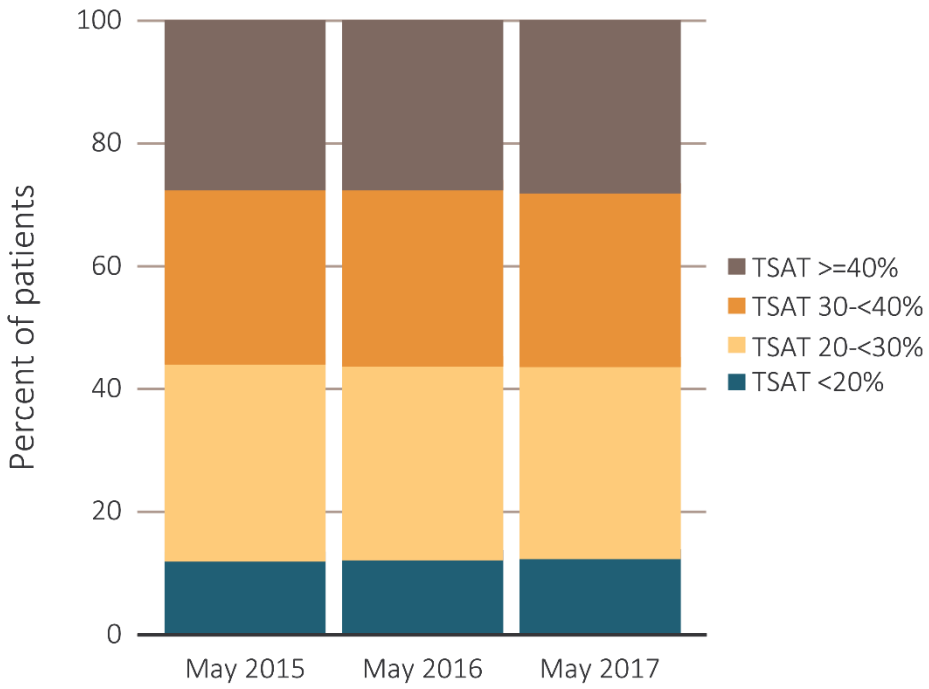


Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among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

As mentioned previously, reporting of iron store measures, transferrin saturation (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 38,940 PD patients in 2015 versus 46,583 PD patients in 2017. TSAT was reported for 39,957 PD patients in 2015 compared to 47,539 PD patients in 2017.

Across the three mid-year cross-sections shown in Figures 2.11 and 2.12, the distribution of TSAT levels among PD patients on dialysis ≥90 days did not differ appreciably, whereas a gradual shift to somewhat higher serum ferritin levels has been seen from May 2015 to May 2017. Averaged across the three years, 12.9% of patients had a TSAT<20%, with 31.7%, 28.5%, and 27.0% of patients having levels of 20% to <30%, 30% to <40%, and ≥40%. No distinctive differences were seen in 2017 TSAT levels across most of the patient characteristics displayed in Table 2.3, except with a slightly greater prevalence of high TSAT levels (≥40%) seen for patients of ages <45 years compared to older aged patients. Across the 2015-2017 period, on average, 13.1% of patients had a serum ferritin ≤200 ng/mL, with 25.5%, 23.3%, 22.5%, and 15.7% of patients having levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. Similar to HD patients, 2017 serum ferritin levels were higher among PD patients of older age and among females compared to males, whereas patients with cystic kidney disease as the primary cause of ESRD had somewhat lower serum ferritin levels (Table 2.4).

vol 2 Figure 2.11 Distribution of TSAT levels in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, May 2015, 2016, and 2017



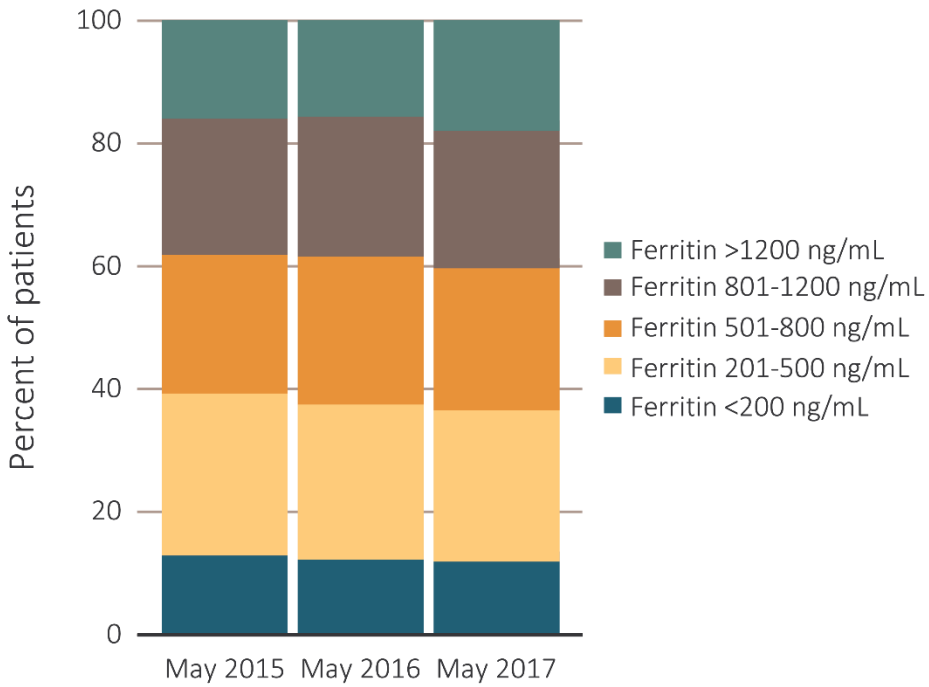
Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. Dialysis patients on treatment for ESRD at least 90 days before the time of measurement of TSAT level for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; TSAT, transferrin saturation.

vol 2 Table 2.3 TSAT by age, sex, race, and primary ESRD cause in peritoneal dialysis patients, May 2017

	N	TSAT <20%	TSAT 20-<30%	TSAT 30-<40%	TSAT≥40%
Overall	**47,539**	**13.1%**	**31.3%**	**28.3%**	**27.3%**
Age					
0-21	300	12.3	24.3	25.0	38.3
22-44	8,659	12.7	29.5	26.2	31.6
45-64	21,217	13.4	32.1	28.1	26.5
65-74	11,020	13.2	31.6	29.6	25.6
75+	6,343	12.7	30.5	29.9	26.9
Sex					
Male	26,512	13.0	31.8	28.6	26.6
Female	21,027	13.3	30.6	28.0	28.2
Race					
White	31,623	13.5	31.6	28.4	26.5
Black/African American	11,611	12.4	31.3	28.5	27.9
American Indian or Alaska Native	438	15.5	30.6	28.1	25.8
Asian	3,044	11.3	28.5	26.9	33.3
Primary cause of ESRD					
Diabetes	18,107	13.4	32.6	29.0	25.0
Hypertension	13,487	12.6	30.2	29.1	28.0
Glomerulonephritis	8,338	13.2	30.3	26.4	30.1
Cystic Kidney	2,366	13.7	34.1	28.8	23.4
Other/Unknown	4,959	13.1	29.4	26.7	30.8

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March through May of 2017. 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, 2017 and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease; 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 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May for years 2015, 2016, and 2017. 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. Figure includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

vol 2 Table 2.4 Serum ferritin by age, sex, race, and primary ESRD cause in peritoneal dialysis patients, May 2017

	N	Ferritin <200 ng/mL	Ferritin 201-500 ng/mL	Ferritin 501-800 ng/mL	Ferritin 801-1200 ng/mL	Ferritin >1200 ng/mL
Overall	**46,583**	**12.7**	**24.7**	**23.1**	**22.4**	**17.2**
Age						
0-21	289	30.5	24.9	19.0	14.9	10.7
22-44	8,488	14.3	27.6	22.6	21.0	14.4
45-64	20,796	12.1	24.5	23.5	22.7	17.3
65-74	10,787	12.0	23.3	22.9	23.4	18.5
75+	6,223	12.6	23.7	23.3	21.7	18.8
Sex						
Male	25,983	13.3	26.4	23.7	21.6	15.1
Female	20,600	11.9	22.5	22.4	23.3	19.9
Race						
White	30,960	14.1	25.9	23.3	21.5	15.1
Black/African American	11,366	9.5	21.7	22.6	24.3	21.9
American Indian or Alaska Native	441	12.5	32.0	22.5	18.1	15.0
Asian	2,997	10.0	22.4	23.0	23.6	21.1
Primary cause of ESRD						
Diabetes	17,709	11.6	25.6	24.5	22.3	16.0
Hypertension	13,233	12.5	23.6	22.4	22.7	18.9
Glomerulonephritis	8,164	12.7	23.4	22.1	23.7	18.1
Cystic Kidney	2,311	20.9	29.0	20.2	19.0	10.9
Other/Unknown	4,892	12.9	24.0	23.2	21.3	18.6

Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for March to May 2017. 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, 2017, and who were alive through May 31, 2017. Table includes row percentages within demographic categories from May 2017. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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 2016. 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, interpretation of results should be made with this in mind.

In 2012, 23.2 of PD patients received one or more red blood cell transfusions. This has continually declined to 21.7 of PD patients in 2013, 20.2 in 2014, 18.3 in 2015, and 15.1 of PD patients in 2016 having received ≥1 red blood cell transfusions within the indicated year. Across this five-year period, typically 9.3-13.2 of PD patients received one red blood cell transfusion per year, 3.2-5.3 received two per year, 1.2-2.1 received three, and 1.4-2.6 received four or more red blood cell transfusions.

Trends in the percentage of PD patients receiving one or more red blood cell transfusions within a month during 2012-2016 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 3.5 in the first quarter of 2012 to 2.0 by the third quarter of 2016. When comparing monthly red blood cell transfusion rates among incident versus prevalent PD patients, transfusion rates were in fact slightly lower for patients on PD <90 days compared with those on PD ≥90 days. From January to November 2016, on average 1.5 of White patients had one or more red blood cell transfusions in a month compared to 1.9 of Black patients and 2.1 of those of Other or Unknown race. Note that since 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 claim 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, 2012-2016

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

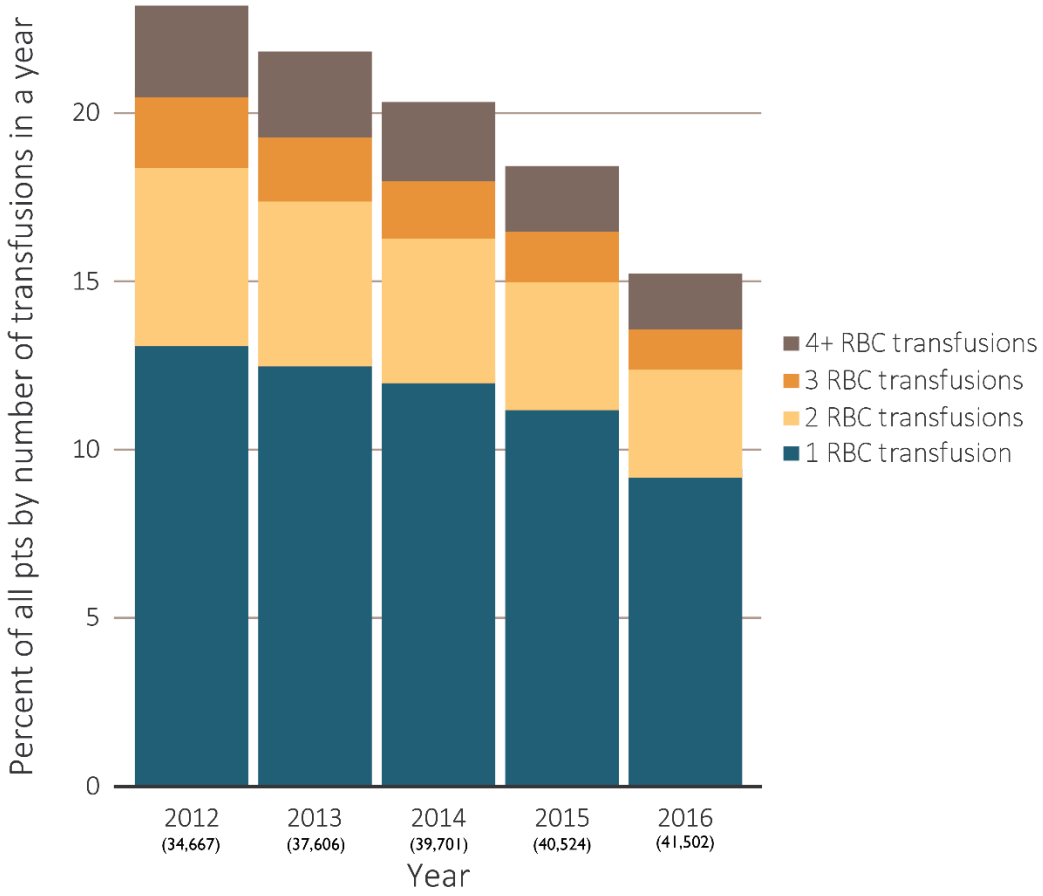
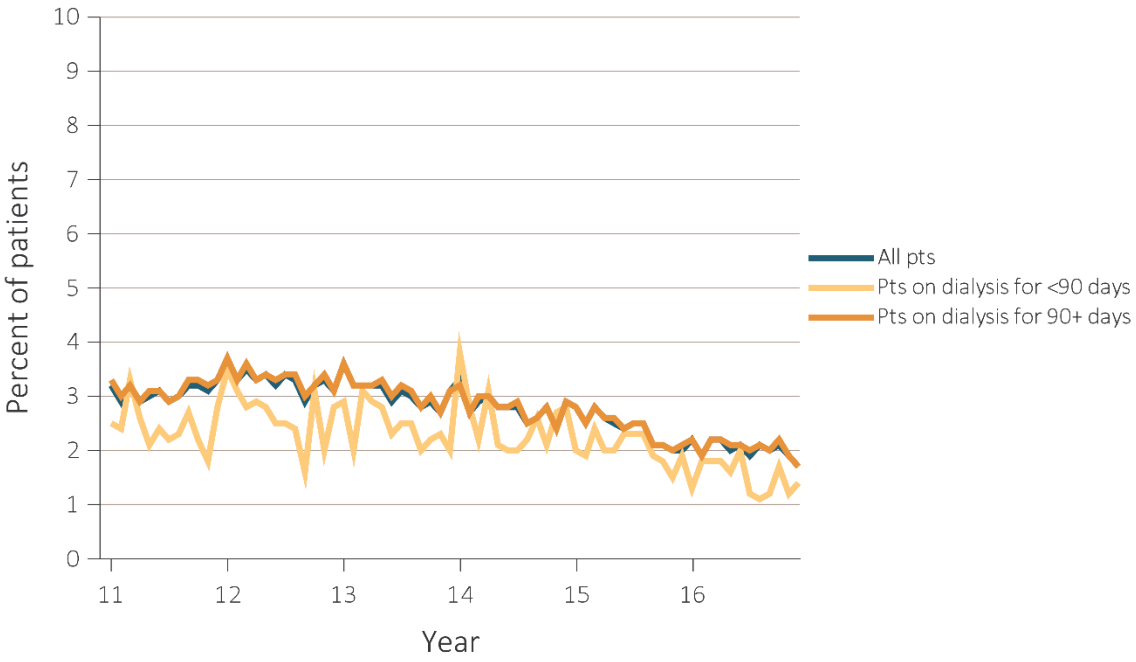


Figure 2.13 continued on next page.

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 claim 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, 2012-2016 (continued)

(b) Percent of all 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. (a) The percent of peritoneal dialysis patients ≥18 years with total number of red blood cell transfusion claims in a given year among dialysis patients having a claim for at least one peritoneal dialysis session during the year. (b) 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. Abbreviations: ESRD, end-stage renal disease; RBC, red blood cell.

Mineral and Bone Disorder Marker Management

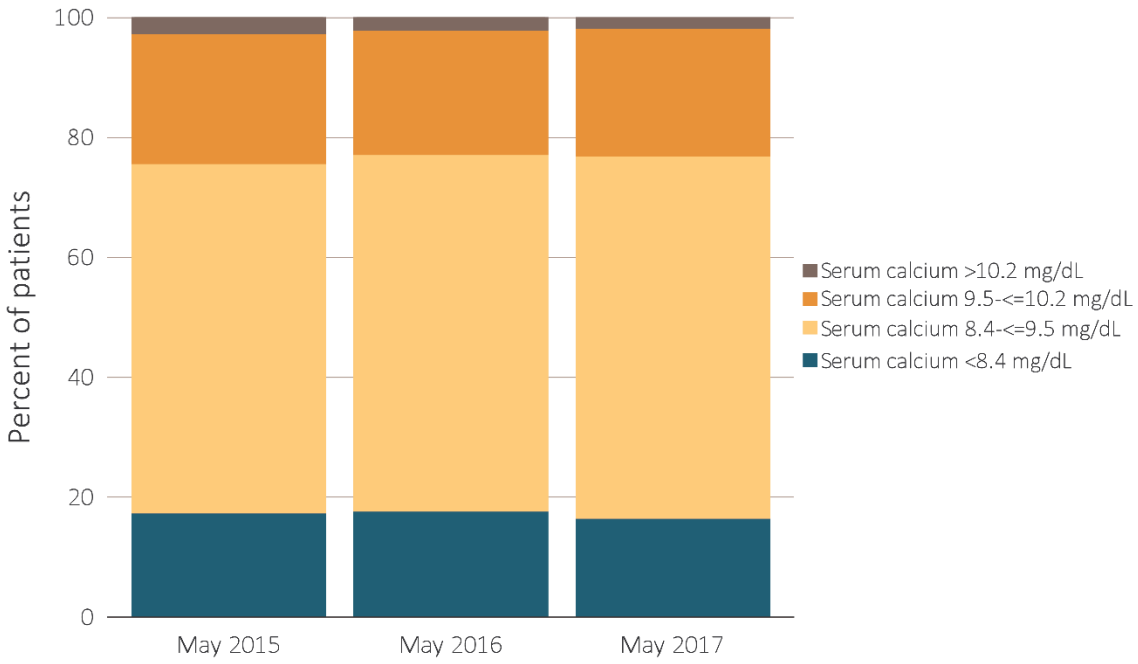
Evidence from basic scientific and epidemiological studies supports the role of abnormalities in markers of mineral and bone metabolism in the pathogenesis of vascular calcifications and cardiovascular disease—major causes of increased hospital admissions and mortality in the chronic dialysis population. Specifically, elevated levels of calcium, phosphorus, and parathyroid hormone (PTH) have been associated with increased cardiovascular events and mortality. Very low serum calcium, phosphorus, and PTH 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 2015 and 2017, no substantial change was observed in serum calcium distributions. The majority of 2017 patients (HD: 60.5, PD: 57.5) had calcium levels within the normal reference range (8.4-9.5 mg/dL), while a very small percentage (HD: 1.3, PD: 1.9) had particularly elevated serum calcium levels of >10.2 mg/dL, a cut point that reflects the quality measure that is currently included in the QIP and DFC

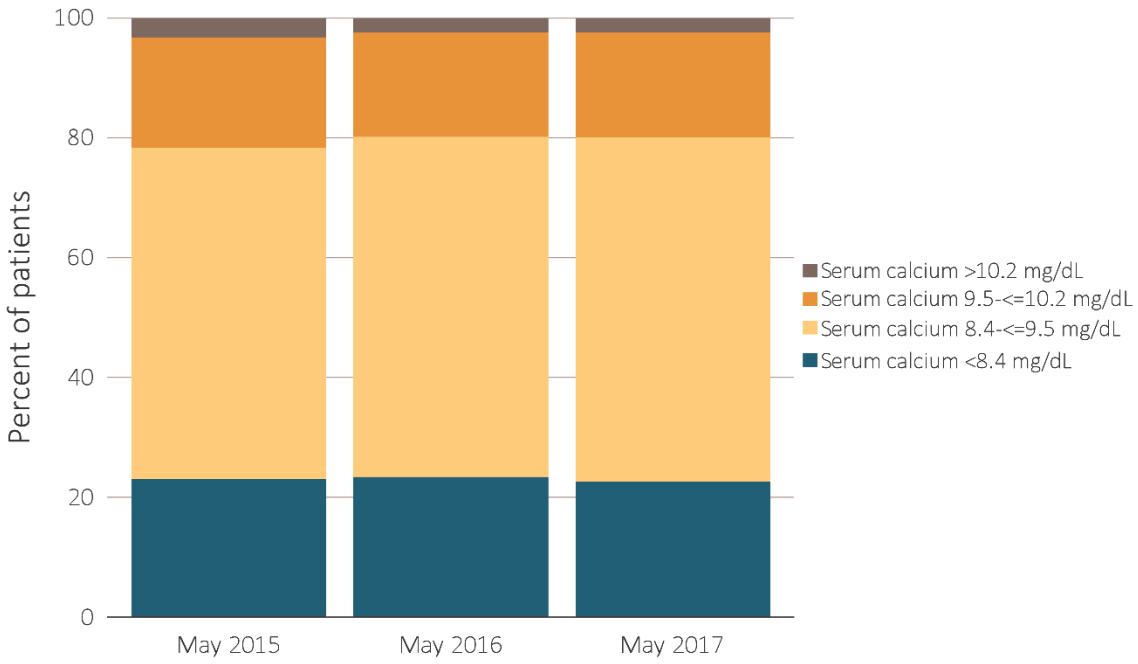
programs based on associations with cardiovascular mortality above that level. The May 2017 prevalence of very low calcium levels (<8.4 mg/dL) was higher in patients on PD, at 23.1, than for HD patients at 16.9, which may be due in part to lower levels of serum albumin levels among patients on PD.

vol 2 Figure 2.14 Distribution of serum calcium levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, May 2015, 2016, and 2017



Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May for years 2015, 2016, and 2017. 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. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network ESRD, end-stage renal disease.

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 2015, 2016, and 2017

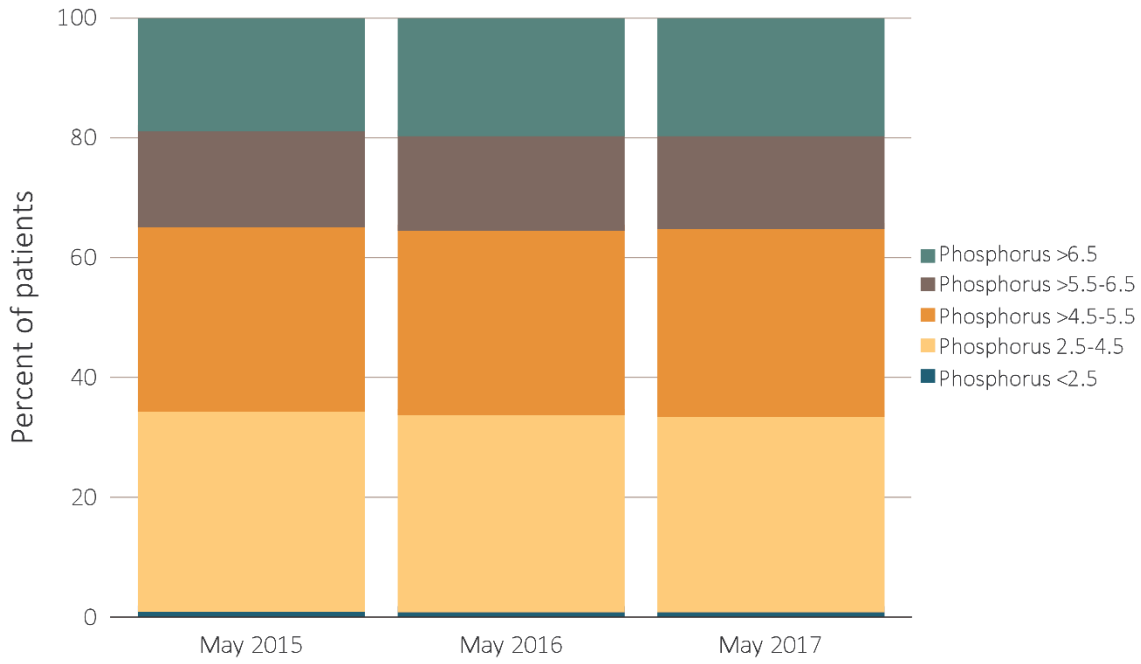


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May for years 2015, 2016, and 2017. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of May 1 of that year and who were alive through May 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network ESRD, end-stage renal disease.

Serum Phosphorus

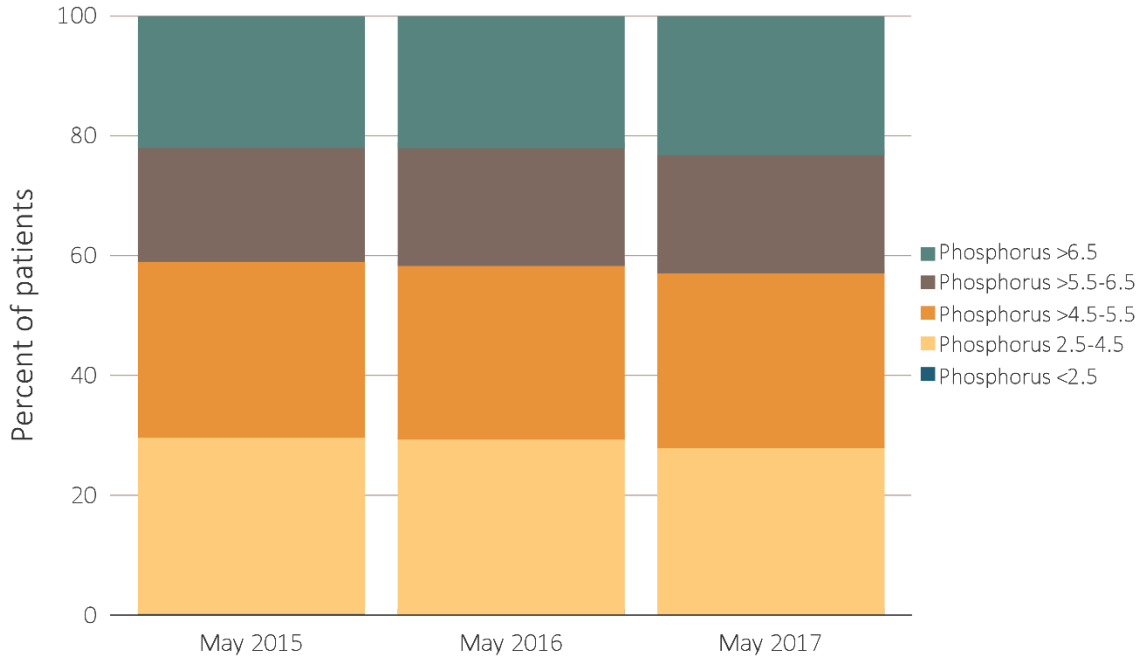
Figures 2.16 and 2.17 illustrate the distributions of serum phosphorus levels among adult HD and PD patients. Between 2015 and 2017, there has been little change in mean serum phosphorus among HD and PD patients (HD: from 5.30 to 5.31 mg/dL; PD: from 5.49 to 5.54 mg/dL). Both the 2009 and 2017 KDIGO CKD-Mineral and Bone Disorder (MBD) guidelines recommend maintaining serum phosphorus levels within the normal laboratory reference range, which is typically between 2.5 and 4.5 mg/dL. Among HD patients in May 2017, approximately two-thirds (66.1) had serum phosphorus >4.5 mg/dL. This percentage was even higher among patients on PD (71.6), 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 2015 to 2017 CROWNWeb data, 1.3-1.4 of HD patients and 0.5-0.7 of PD patients had serum phosphorus levels <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 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2015, May 2016, and May 2017. 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. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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 2015, 2016, and 2017



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for May 2015, May 2016, and May 2017. 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. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; ESRD, end-stage renal disease.

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.

As shown in Figure 2.18, from 2004 to 2016, Medicare claims showed a slight increase in the percentage of ESRD patients with diabetes who received at least one glycosylated hemoglobin test (HbA1c; 81.8 in 2004 to 83.4 in 2016). In 2016, 93.6 of Medicare PPO, 93.5 of Medicare HMO, 89.3 of commercial PPO, 90.6 of commercial HMO, and 86.7 of Medicaid HMO patients 18-75 years of age with a diagnosis of type 1 or type 2 diabetes had at least one HbA1c test ("Comprehensive Diabetes Care," National Committee for Quality Assurance, 2018). However, the percentage of ESRD patients with diabetes who received two or more HbA1c tests decreased from 71.7 in 2004 to 68.9 in 2016. The American Diabetes Association has recommended that HbA1c tests be performed at least 2 times a year in patients who are meeting treatment goals and who have stable glycemic control and more frequently in patients whose therapy has changed or who are not meeting glycemic goals. The percentage of ESRD patients with diabetes who received at least one lipid test increased steadily from 2004 to 2010 (68.8 to 81.4), followed by a steady decrease between 2010 and 2016 (81.4 in 2010 to 68.9 in 2016; Figure 2.18). In 2013, 87.7 of Medicare PPO, 88.9 of Medicare HMO, 81.3 of Commercial PPO, 84.9 of Commercial HMO, and 76.0 of Medicaid HMO patients 18-75 years of age with a diagnosis of diabetes had at least one lipid test ("HEDIS Measures of Care," National Committee for Quality Assurance, 2014). The National Committee for Quality Assurance retired its LDL-C screening measure in 2013.

The lower rates of HbA1c testing in diabetic patients with ESRD 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 2016, 46.9 of diabetic ESRD patients had at least one diabetic eye exam (Figure 2.18). This did not meet the Healthy People 2020 target of 58.7 (2018). In 2016, 69.6 of Medicare PPO, 70.4 of Medicare HMO, 47.5 of commercial PPO, 53.6 of commercial HMO, and 54.9 of Medicaid HMO patients 18-75 years of age with a diagnosis of type 1 or type 2 diabetes had at least one diabetic eye exam ("Comprehensive Diabetes Care," National Committee for Quality Assurance, 2018). A similar pattern exists for the patients receiving ≥2 HbA1c tests, at least one lipid test, and at least one diabetic eye exam—approximately 29 in the most recent data year, down from a high of 33 in 2010. 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, 2004-2016

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.

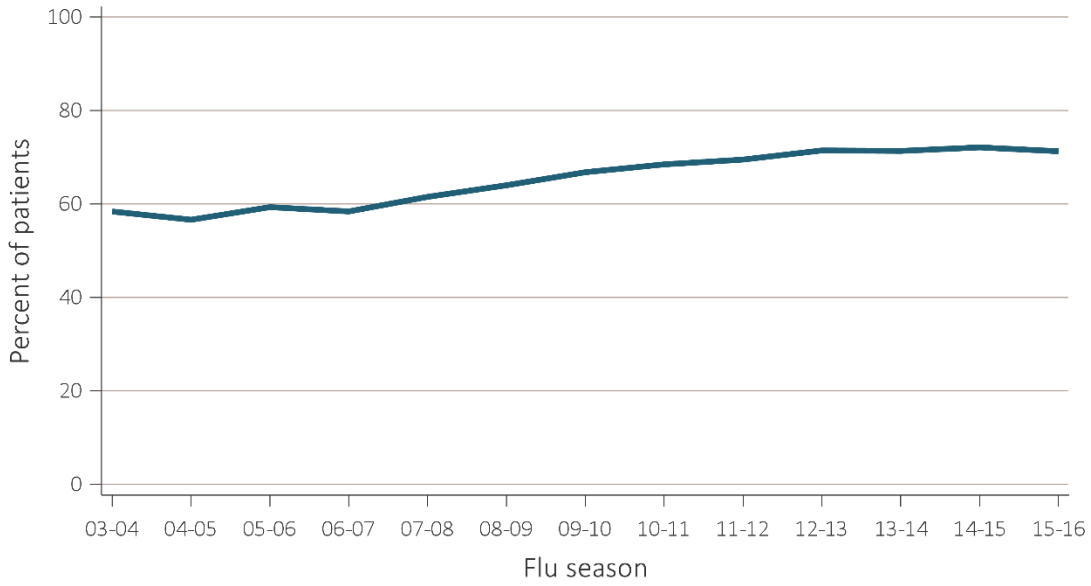
Vaccination

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 59.3 in the 2005-2006 season to 71.3 in the 2015-2016 season, though rates appear to have plateaued in the last few reporting years (Figure 2.19.a). These reported percentages may be underestimates, however, as they were derived from claims data that may not completely capture all vaccination events.

The percentage of patients vaccinated is presented by modality stratified further by age due to substantially different distributions of age between the transplant and dialysis populations (Figures 2.19.b-d). Overall, HD patients were vaccinated at the highest frequency—78.0 in the most current data—compared with 76.1 of PD patients and 48.9 of kidney transplant patients in the 2015-2016 season. Among the transplant patients, the vaccination frequency has been dropping since the 2013-2014 season for the younger age categories (0-64) (Figure 2.19.d). This trend may in part relate to higher transplant rates in these groups in recent years, as vaccination is often delayed after a new transplant due to concerns about an ineffective immune response or the possibility of triggering an acute rejection episode. 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 70.4 in the 2015-2016 season (Figures 2.19.e and 2.19.f).

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 and hemodialysis treatment, (c) by age and peritoneal dialysis, (d) by age and transplantation, (e) by race, and (f) by ethnicity, Medicare data, 2003-2016

(a) Overall



(b) Age and hemodialysis treatment

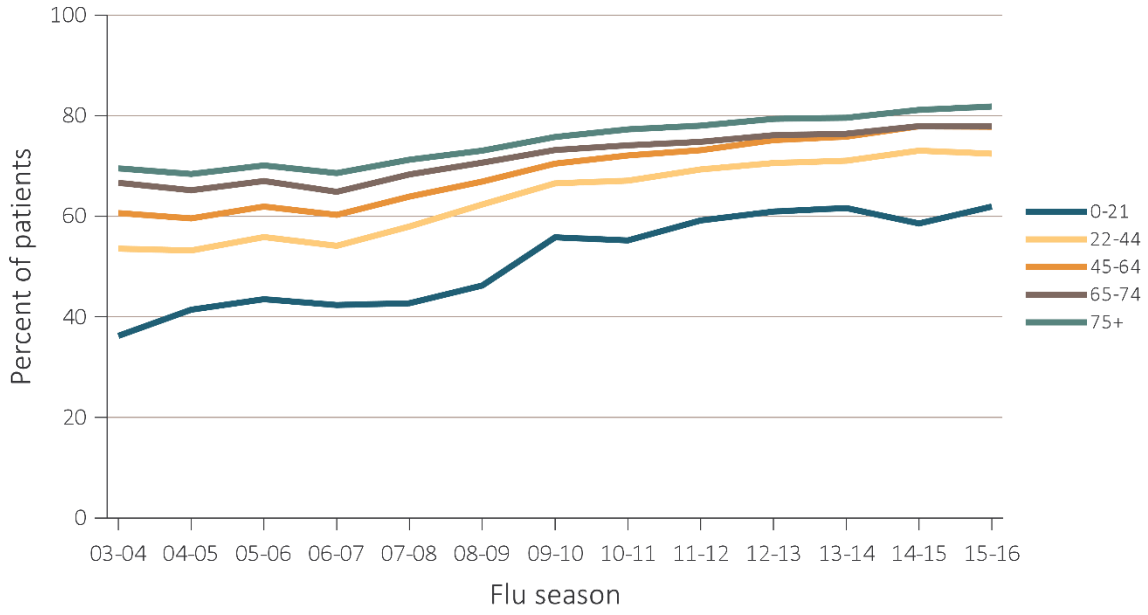
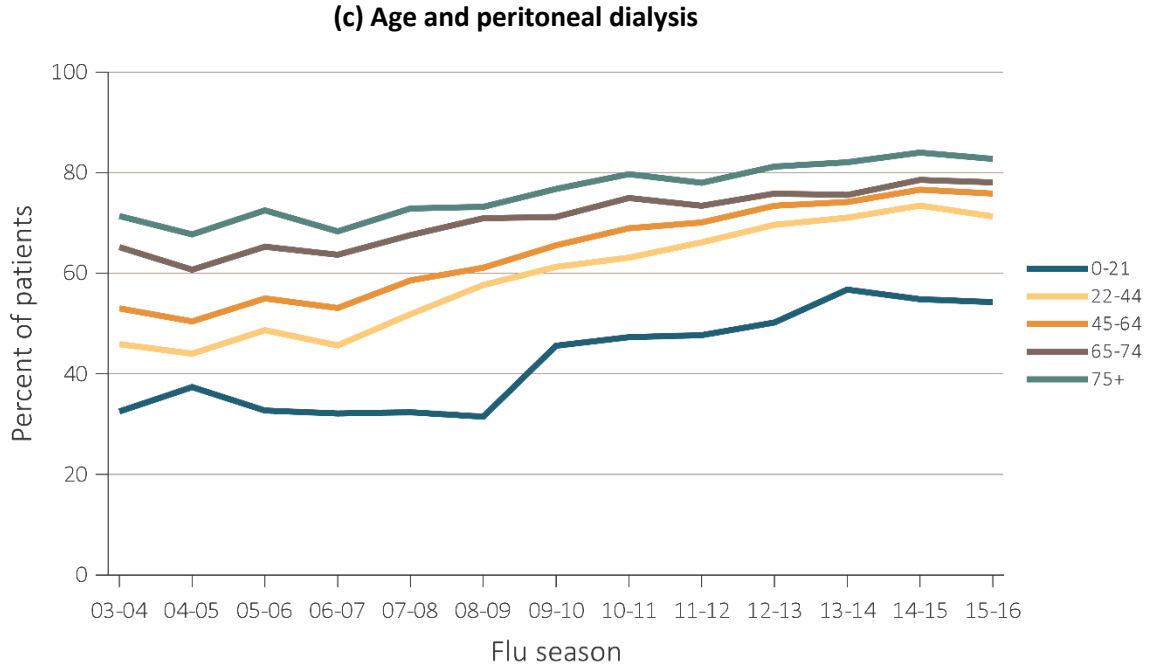


Figure 2.19 continued on next page.

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 and hemodialysis treatment, (c) by age and peritoneal dialysis, (d) by age and transplantation, (e) by race, and (f) by ethnicity, Medicare data, 2003-2016 (continued)



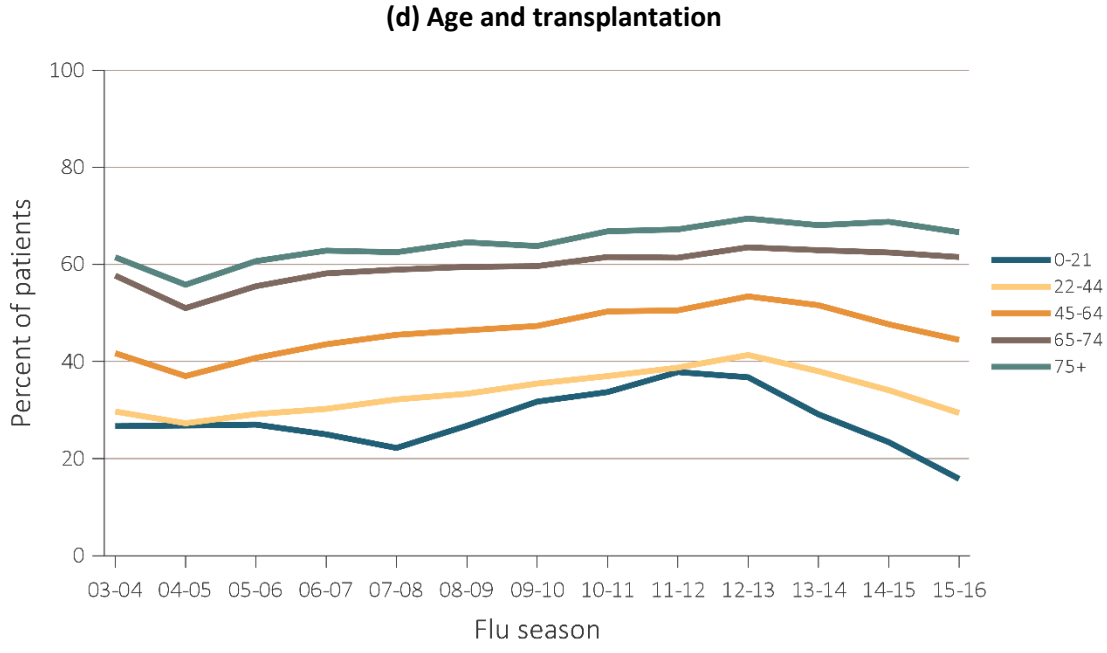
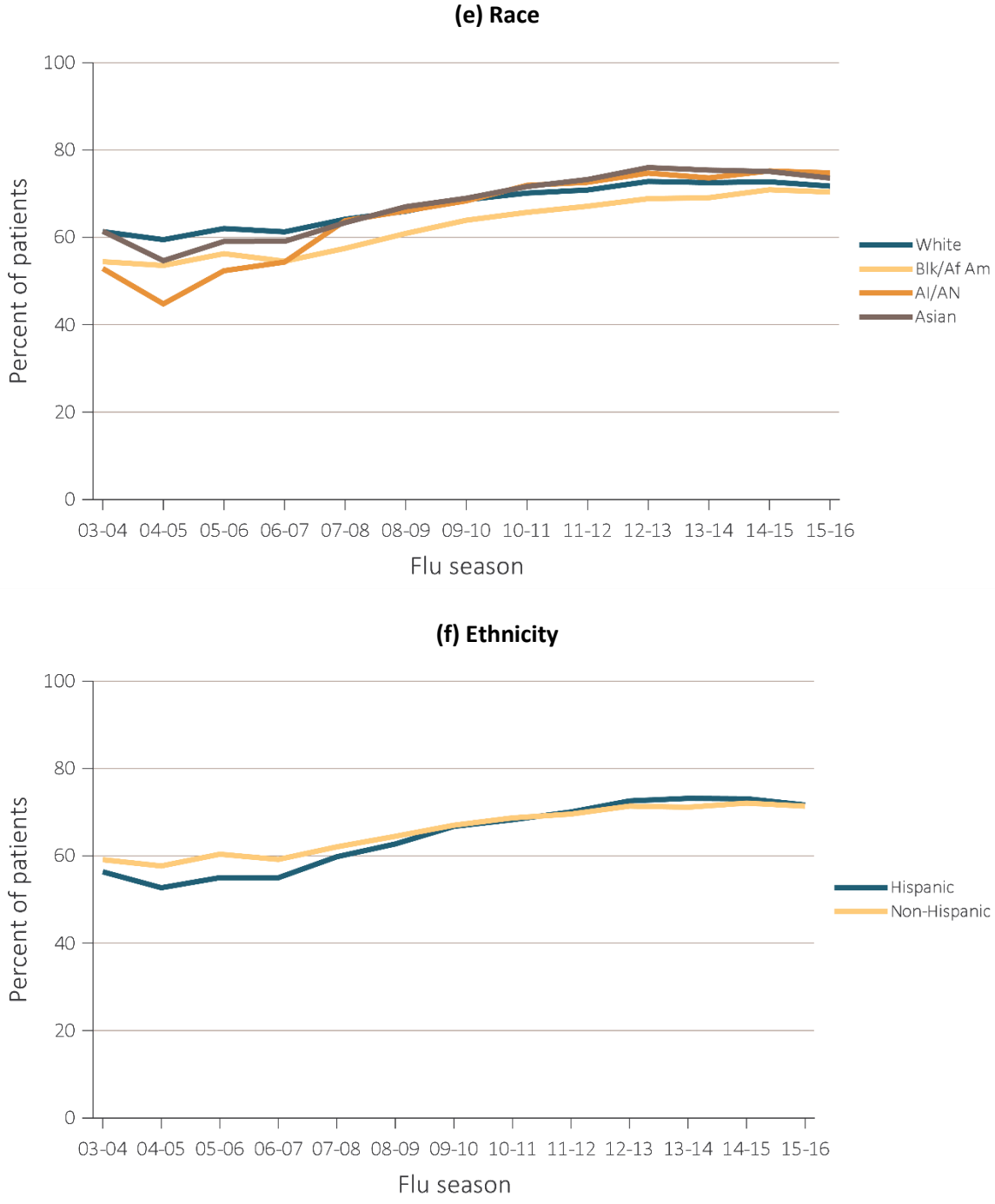


Figure 2.19 continued on next page.

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 and hemodialysis treatment, (c) by age and peritoneal dialysis, (d) by age and transplantation, (e) by race, and (f) by ethnicity, Medicare data, 2003-2016 (continued)



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: AI, American Indian; AN, Alaska Native; Blk/Af Am, Black/African American; ESRD, end-stage renal disease.

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