

Chapter 3: Clinical Indicators and Preventive Care

Anemia

- The majority (63.3%) of hemodialysis patients in December 2015 had Hgb levels between 10-12 g/dL, while 14.7% had Hgb \geq 12 g/dL, 6.8% had Hgb less than 9 g/dL, and 15.2% had Hgb between 9-10g/dL, with the mean Hgb being 10.8/dL (Figure 3.1.b).
- The majority (55.6%) of peritoneal dialysis patients in December 2015 had Hgb levels between 10-12 g/dL, while 20.3% had Hgb \geq 12 g/dL, 8.0% had Hgb less than 9 g/dL, and 16.1% had Hgb between 9-10 g/dL, with the mean Hgb being 10.9 g/dL (Figure 3.1.b).
- From December 2013 to December 2014, EPO doses increased by 1.5% in hemodialysis patients and 4.5% in peritoneal dialysis patients in the United States. In 2014, average monthly EPO doses were approximately 10,524 units/week and 9,716 units/week for hemodialysis and peritoneal dialysis patients, respectively (Figures 3.2.a and 3.8.a).
- Little change was seen in IV iron use (60.6% to 61.2%) and IV iron dose (296.4 mg to 295.6 mg) from 2013 to 2014 in U.S. hemodialysis patients (Figure 3.4).
- Little change was seen in IV iron use (23.8% to 24.7%) and IV iron dose (194.3 mg to 195.5 mg) from 2013 to 2014 in U.S. peritoneal dialysis patients (Figure 3.10).
- Serum ferritin levels have fluctuated slightly in all dialysis patients from 2013 to 2015, with 54.8% of hemodialysis patients and 39.2% of peritoneal dialysis patients having serum ferritin levels $>$ 800 ng/mL in December 2015 (Figures 3.6 and 3.12).

Mineral and Bone Disorder

- In December 2015, 58.5% of hemodialysis and 56.5% of peritoneal dialysis patients had calcium levels within a typical laboratory reference range (8.4-9.5 mg/dL). About 2% of patients receiving either dialysis modality had calcium levels $>$ 10.2 mg/dL, whereas 17.7% of hemodialysis patients and 23.4% of peritoneal dialysis patients had calcium levels $<$ 8.4 mg/dL (Figures 3.14 and 3.15).
- In December 2015, 65.5% of hemodialysis patients and 69.4% of peritoneal dialysis patients had serum phosphorus levels $>$ 4.5 mg/dL (Figures 3.16 and 3.17).

Preventive Care

- In 2014, only 32.8% of ESRD patients with diabetes received comprehensive diabetes monitoring (defined as at least one HbA1c test, one lipid test, and one dilated eye exam). This is a decline from 36.4% in 2010 (Figure 3.18).
- 70.7% of patients received an influenza vaccination in the 2013-2014 flu season, which is still below the Healthy People 2020 (HP2020) target of 90%. Although stable over the last two seasons, the percent vaccinated has increased from 58.4% a decade prior (Figure 3.19.a).

Introduction

Given the high morbidity and mortality of individuals in the end-stage renal disease (ESRD) population on dialysis, initiatives aimed at quality improvement 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) (www.dialysisdata.org), 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 and the data collection system is known as the Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb). This system, which was implemented nationally in May 2012, allows for monthly submission of selected laboratory and clinical data from facilities for patients under their care; however, the system is still evolving and not all data are fully captured. This year, CROWNWeb data are used in this chapter for analyses on dialysis adequacy, bone and mineral disorders, and selected anemia measures.

Methods

This chapter uses data from the Centers for Medicare & Medicaid Services (CMS). Details of the data source are described in the [Data Sources](#) section of the *ESRD Analytical Methods* chapter.

See the section on [Chapter 3](#) in the *ESRD Analytical Methods* chapter for a detailed explanation of analytical methods used to generate the study cohorts, figures, and tables in this chapter.

Clinical Indicators

In Figure 3.1, we present CROWNWeb data from December 2015 on a selection of clinical indicators relating to dialysis adequacy, achieved hemoglobin (Hgb) level, and hypercalcemia. Figure 3.1.a shows that achievement of dialysis adequacy targets for hemodialysis is nearly universal, with 96.4% of patients obtaining a single pool Kt/V ≥ 1.2 (for more information about Kt/V see the *Glossary*). Achievement of the dialysis adequacy target for peritoneal dialysis (a weekly Kt/V ≥ 1.7) is somewhat lower, at 89.0% (Figure 3.1.a).

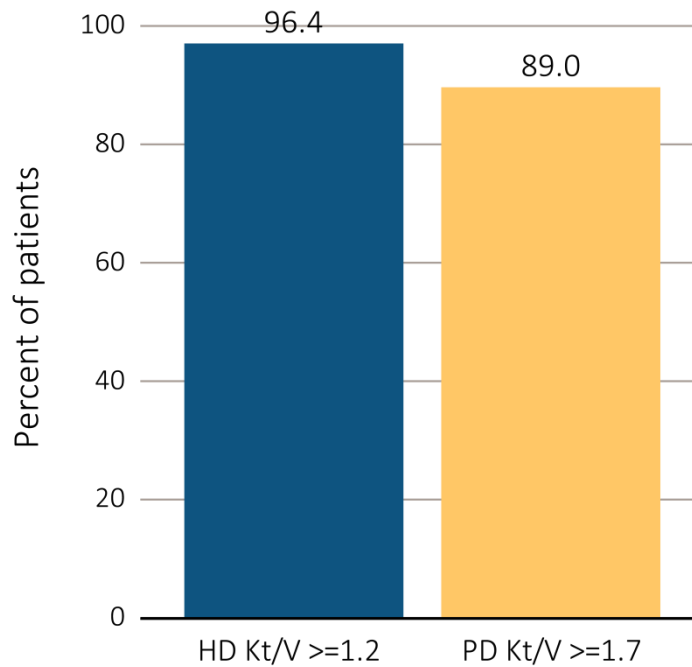
Views on anemia treatment with erythropoiesis-stimulating agents (ESAs) have evolved in recent

years, as safety concerns emerged from controlled clinical trials with CKD patients who experienced greater risks of death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level 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 approaches or exceeds 11 g/dL. Current guidelines do not specify an appropriate lower limit. This has resulted in generally lower Hgb levels among dialysis patients. Using CROWNWeb data, Figure 3.1.b presents a more representative view of Hgb levels for the dialysis population than was previously possible, as it includes data from both Medicare and non-Medicare insured patients. Among hemodialysis patients (both ESA-treated and non-treated), the majority (63.3%) have Hgb levels in the range of 10-12 g/dL, with 14.7% having Hgb ≥ 12 g/dL in December 2015. The pattern is similar with peritoneal dialysis patients, though a somewhat higher percentage (20.3%) have Hgb ≥ 12 g/dL. Later in this chapter, Medicare claims (updated through 2014) are utilized for the anemia analyses in order to provide information on time trends. In addition, CROWNWeb data are used to describe iron indices (ferritin and transferrin saturation).

In Figure 3.1.c we present CROWNWeb data on the percentage of dialysis patients having serum calcium levels >10.2 mg/dL as of December 2015, and calculated as a three-month rolling average, which is similar to methods utilized by the QIP. The rationale for this measure is to encourage avoidance of hypercalcemia given its associations with vascular calcifications and cardiovascular events. The percent of patients with hypercalcemia for both modalities has declined compared to December 2014. Later in the chapter, we present additional CROWNWeb data on trends in serum calcium and phosphorus levels.

vol 2 Figure 3.1 ESRD clinical indicators: (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; and (c) percentage of dialysis patients with serum calcium >10.2 mg/dL by modality, CROWNWeb data, December 2015

(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

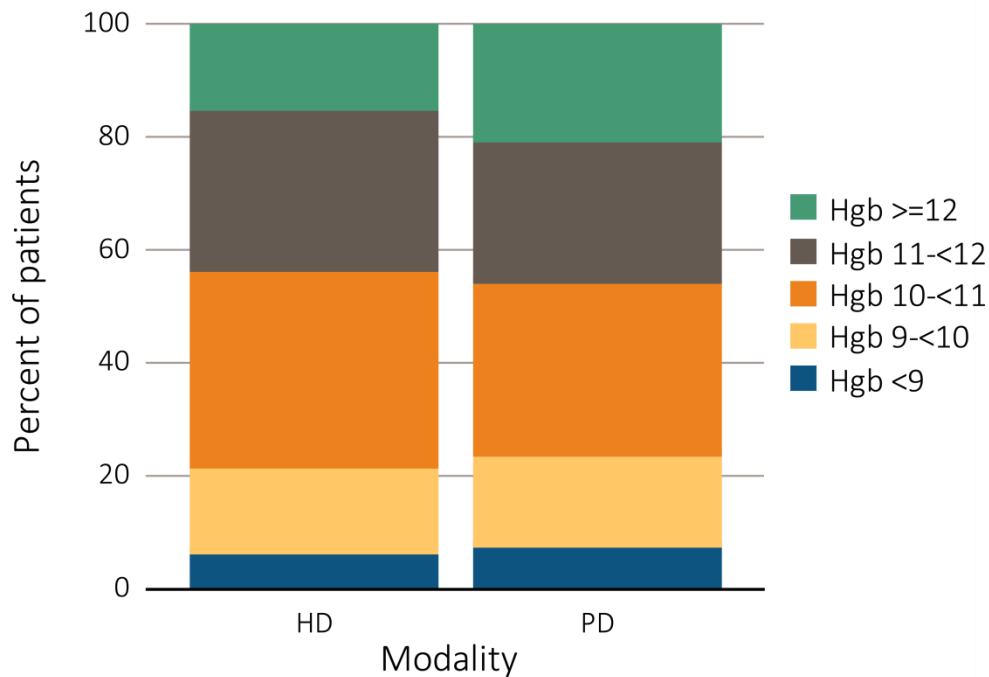
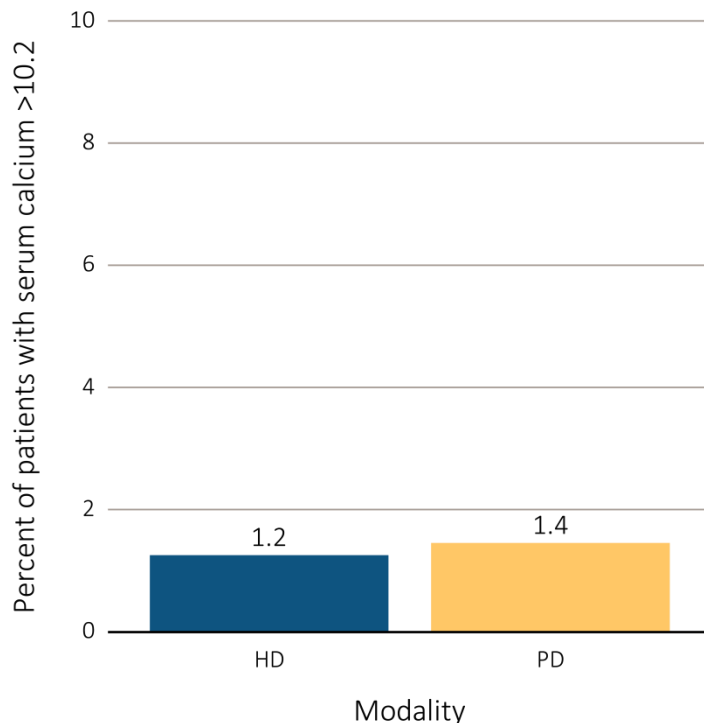


Figure 3.1 continued on next page.

vol 2 Figure 3.1 ESRD clinical indicators: (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; and (c) percentage of dialysis patients with serum calcium >10.2 mg/dL by modality, CROWNWeb data, December 2015 (continued)

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



Data Source: Special analyses, USRDS ESRD Database. Results shown are for laboratory values reported to CROWNWeb for December 2015, restricted to patients as follows: (a) dialysis patients initiating treatment for ESRD at least 1 year prior to December 1, 2015, and who were alive through December 31, 2015; (b) dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, who were ≥18 years old as of December 1, 2015, and who were alive through December 31, 2015; and (c) hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2015, who were ≥18 years old as of December 1, 2015, and who were alive through December 31, 2015. 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, long-term trends in Hgb levels, ESA use, erythropoietin (EPO) dose, intravenous (IV) iron use, IV iron dose, levels of iron stores, and red blood cell transfusion rates are described through the year 2014 by dialysis modality in CMS claims data. Monthly mean IV iron doses are now provided for years 2005 to 2014 based on CMS claims data. Prior to 2012, to meet CMS billing requirements, Hgb values were only reported by dialysis providers when filing a claim for patients receiving an ESA during the given month. Consequently, Hgb values based on CMS claims data prior to 2012 were restricted to ESA-treated patients. Beginning in 2012, CMS required reporting of Hgb values for all patients, regardless of whether they received an ESA. This allows a comparison of Hgb values for ESA-treated patients to non-ESA treated patients and compared to *all* patients based upon CMS claims data beginning in April 2012.

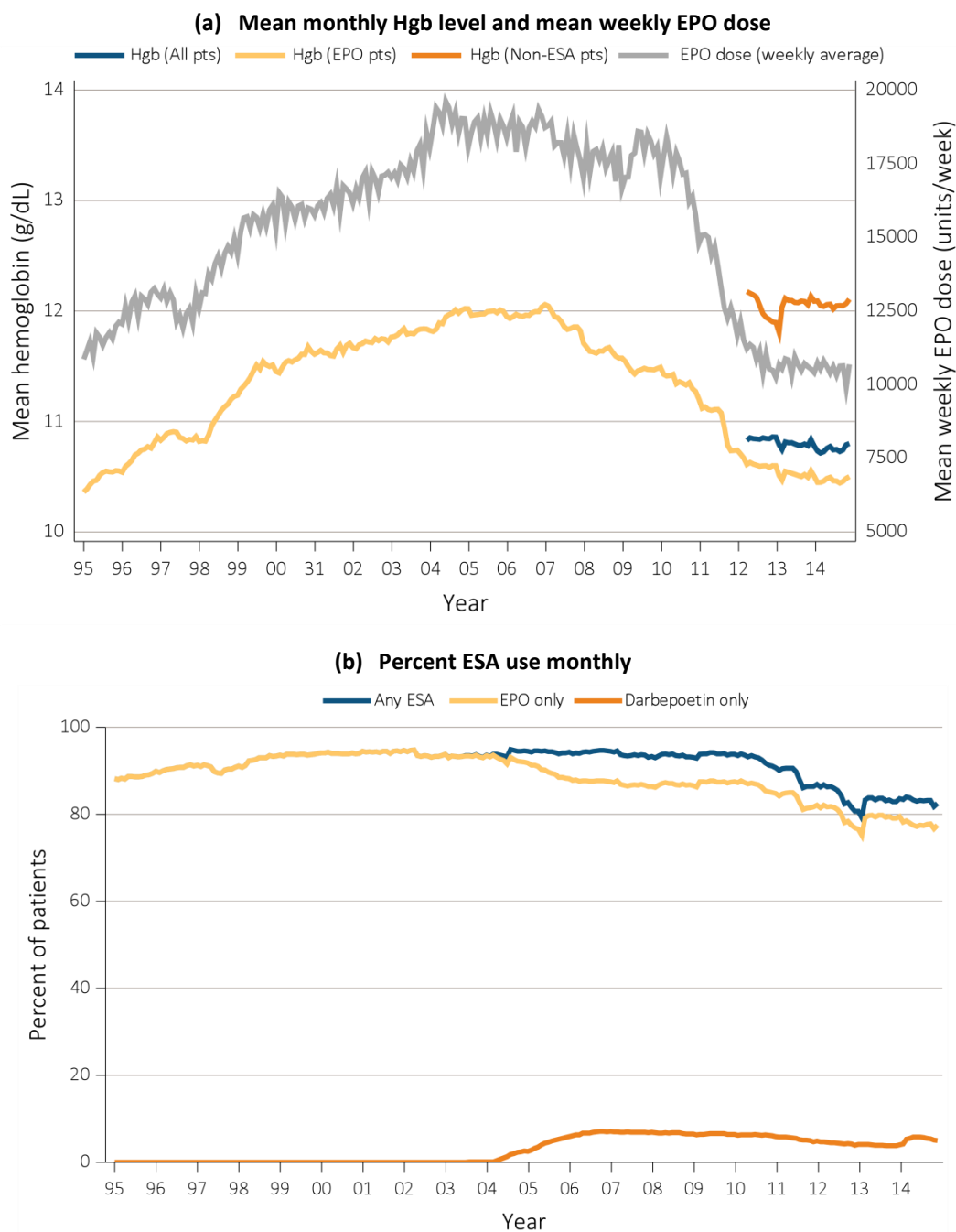
HGB LEVELS, ESA USE, AND EPO DOSE IN HEMODIALYSIS PATIENTS

Claims data indicate that mean Hgb levels have declined substantially since they peaked near 12.0 g/dL in 2007 in ESA-treated hemodialysis patients (Figure 3.2.a). During 2011, the mean Hgb level for ESA-treated

hemodialysis patients declined by 0.5 g/dL from 11.2 g/dL to 10.7 g/dL. Since then, Hgb levels have continued to slowly decline to a mean monthly Hgb of 10.5g/dL in 2014 among *ESA-treated* hemodialysis patients on dialysis ≥ 90 days. Mean monthly Hgb values in 2014 were 10.8 g/dL for *all* hemodialysis patients on dialysis ≥ 90 days and 12.1 g/dL for non-ESA treated patients. Similarly, analyses of CROWNWeb data have indicated a similar mean Hgb level of 10.8 g/dL for *all* hemodialysis patients in December 2014.

Typically, 82%-84% of hemodialysis patients on dialysis for ≥ 90 days had a claim for ESA use during any single month in 2014 (Figure 3.2.b). In most months of 2014, approximately 78% of hemodialysis patients on dialysis ≥ 90 days received EPO and around 5% received darbepoetin. Between December 2006 and December 2014, mean weekly EPO doses (averaged over a month) have declined 44% in hemodialysis patients. Mean weekly EPO doses in 2014 were very similar to those in 2013 (Figure 3.2.a), with the mean weekly EPO dose (averaged over a month) being relatively stable throughout 2014. The mean EPO dose for hemodialysis patients on dialysis ≥ 90 days, when calculated for the prevalent cross-section of these patients in each month of 2014, and then averaged across 12 months, indicated an average weekly EPO dose of $10,524 \pm 70.5$ units/week in 2014.

vol 2 Figure 3.2 Anemia measures among adult hemodialysis patients on dialysis ≥ 90 days: (a) mean monthly Hgb level and mean weekly EPO dose (averaged over a month), and (b) percent ESA use monthly, Medicare claims, 1995-2014

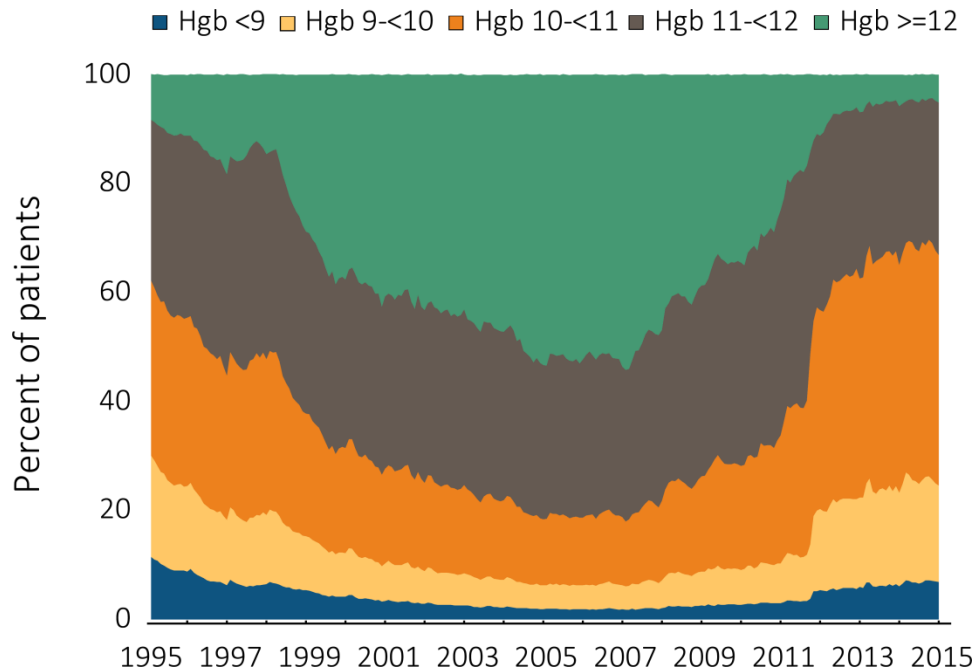


Data Source: Special analyses, USRDS ESRD Database. (a) Mean monthly Hgb level among ESA-treated adult hemodialysis patients on dialysis ≥ 90 days (1995 through 2014) or mean monthly Hgb level among all adult hemodialysis patients (April 2012 to December 2014 only) who, within the given month had a Hgb claim (only the first reported Hgb value in a month was used) and were on dialysis ≥ 90 days; analyses were restricted to patients ≥ 18 years old at the start of the month. Mean weekly EPO (epoetin alfa) dose is shown for hemodialysis patients within a given month who had an EPO claim, were on dialysis ≥ 90 days, and were ≥ 18 years old at the start of the month. EPO dose is expressed as mean EPO units per week averaged over all EPO claims within a given month. (b) Monthly ESA use in all hemodialysis patients who were ≥ 18 years old at the start of the month and were on dialysis ≥ 90 days. “EPO only” use is defined as receiving EPO but not darbepoetin; “Darbepoetin only” use is defined as receiving darbepoetin but not EPO. “Any ESA” use is defined as receiving either or both EPO and Darbepoetin. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2014, a large shift has occurred in the percentage of ESA-treated adult hemodialysis patients in the highest versus lowest categories of Hgb levels (Figure 3.3). The percentage with Hgb <10 g/dL increased from 7% in 2007 to 25% in 2014 among ESA-treated patients on dialysis ≥ 90 days, while the percentage with Hgb ≥ 12 g/dL has declined 10-fold

from 49.6% in 2007 to 4.8% in 2014. Among all (both ESA treated and non-ESA treated) hemodialysis patients on dialysis ≥ 90 days in December 2014, 6% had Hgb <9 g/dL, 15% had Hgb of 9 to <10 g/dL, 65% had Hgb between 10-12 g/dL, and 14% had Hgb ≥ 12 g/dL.

vol 2 Figure 3.3 Distribution of monthly Hgb (g/dL) levels in ESA-treated adult hemodialysis patients on dialysis ≥ 90 days, Medicare claims, 1995-2014



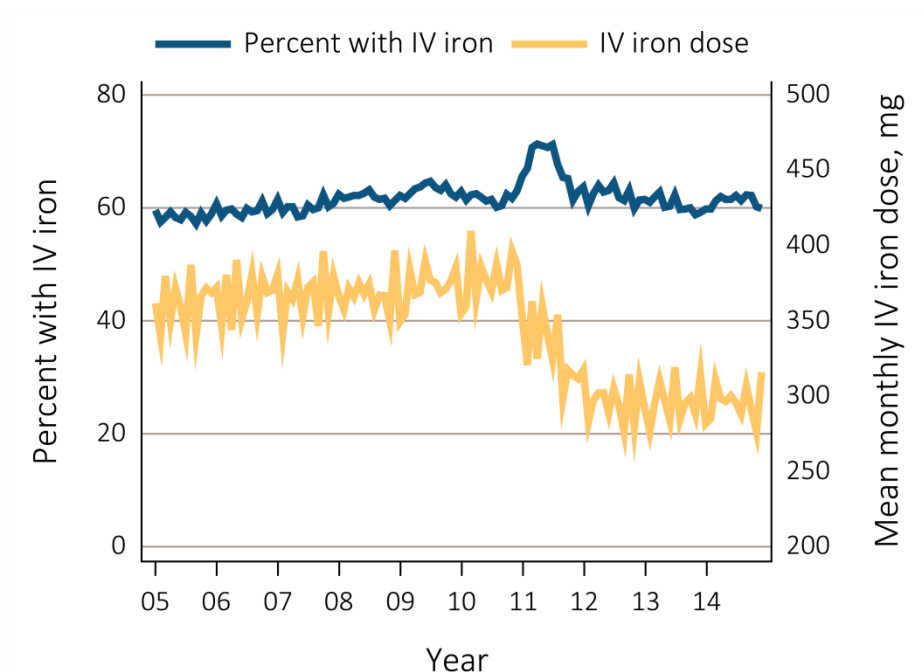
Data Source: Special analyses, USRDS ESRD Database. Distribution among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥ 90 days and ≥ 18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

IV IRON USE, IV IRON DOSE, AND MEASURES OF IRON STORES IN HEMODIALYSIS PATIENTS

Trends in IV iron use for hemodialysis patients from 2005 to 2014 are shown in Figure 3.4. 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 start of the CMS bundled Prospective Payment System (PPS) for dialysis services in January 2011. However, since July 2011, IV iron use has declined steadily to 59.9% by December 2014, which is what it was prior to the start of the bundled PPS in 2011. The trend in

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

vol 2 Figure 3.4 Monthly percent IV iron use and mean monthly IV iron dose in adult hemodialysis patients on dialysis ≥ 90 days, Medicare claims, 2005-2014



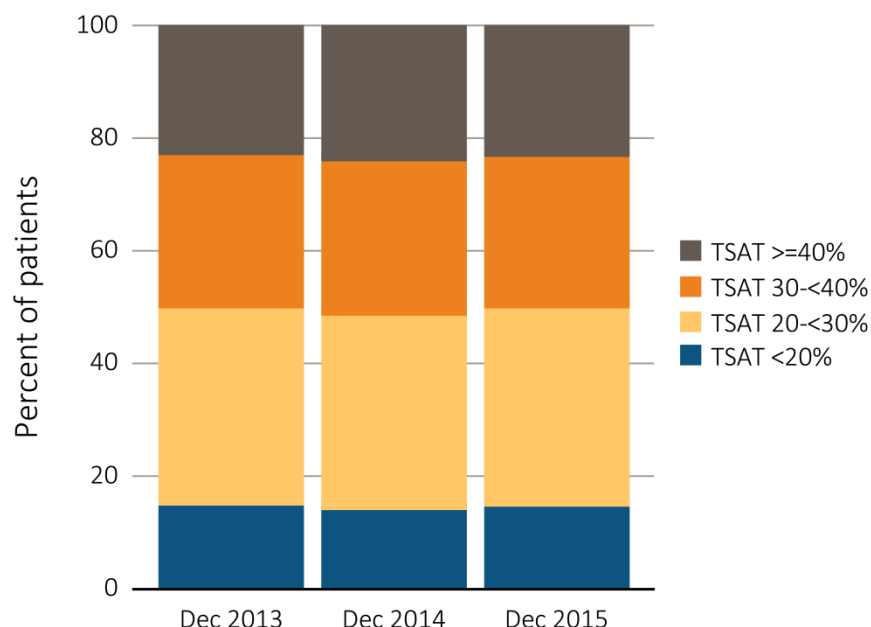
Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis ≥ 90 days and ≥ 18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among patients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

The iron store measures, transferrin saturation (TSAT) and serum ferritin, are now reported by U.S. dialysis units as part of CROWNWeb data collection. Reporting of these measures to CROWNWeb has increased over time. For example, serum ferritin was reported for N=296,869 hemodialysis patients in 2013 versus N=354,937 hemodialysis patients in 2015. Typically, reporting of TSAT levels in hemodialysis patients has been 20%-30% lower than for serum ferritin levels. Due to the changes in reporting of data from facilities over time, the trends noted below should be interpreted cautiously.

The distributions of TSAT (Figure 3.5) and serum ferritin (Figure 3.6) levels among hemodialysis

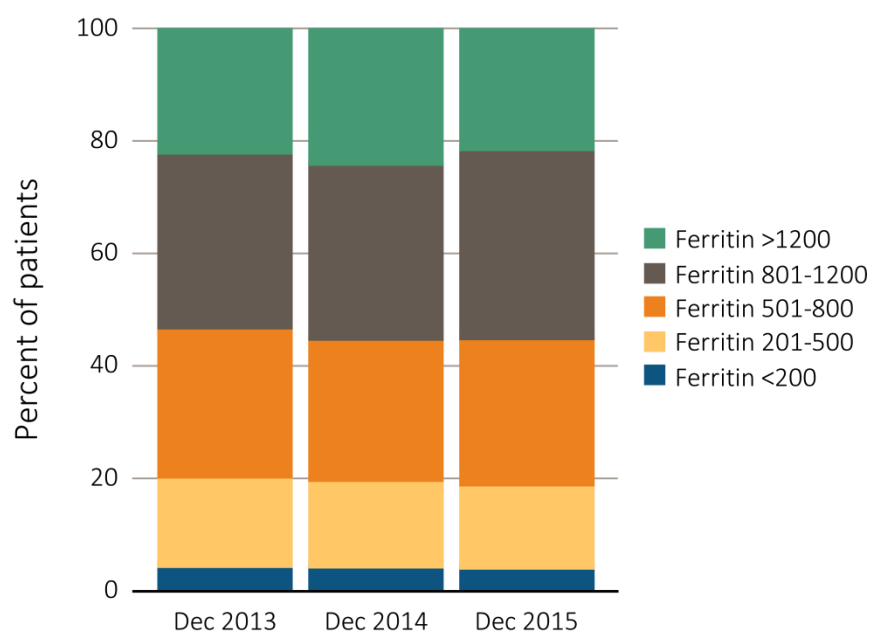
patients on dialysis ≥ 90 days did not differ appreciably during 2013-2015. Averaged across this time period, 15.1% of patients had a TSAT $< 20\%$, with 34.9%, 27.2%, and 22.9% of patients having TSAT levels of 20% to $< 30\%$, 30% to $< 40\%$, and $\geq 40\%$, respectively. The percentage of patients with TSAT $< 20\%$ remained relatively stable varying from 14.6% to 15.4%. During 2013-2015, on average, 4.6% of patients had serum ferritin ≤ 200 ng/mL, with 15.4%, 25.9%, 31.9%, and 22.3% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and > 1200 ng/mL, respectively. The mean serum ferritin level increased slightly from 893 to 901 ng/mL from December 2013 to December 2015.

vol 2 Figure 3.5 Distribution of TSAT levels (%) in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2013, December 2014, and December 2015. 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 December 1 of that year and who were alive through December 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 3.6 Distribution of the most recent value of serum ferritin (ng/mL) level taken between October and December in adult hemodialysis patients on dialysis for at least 90 days, CROWNWeb data, 2013-2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. 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 December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

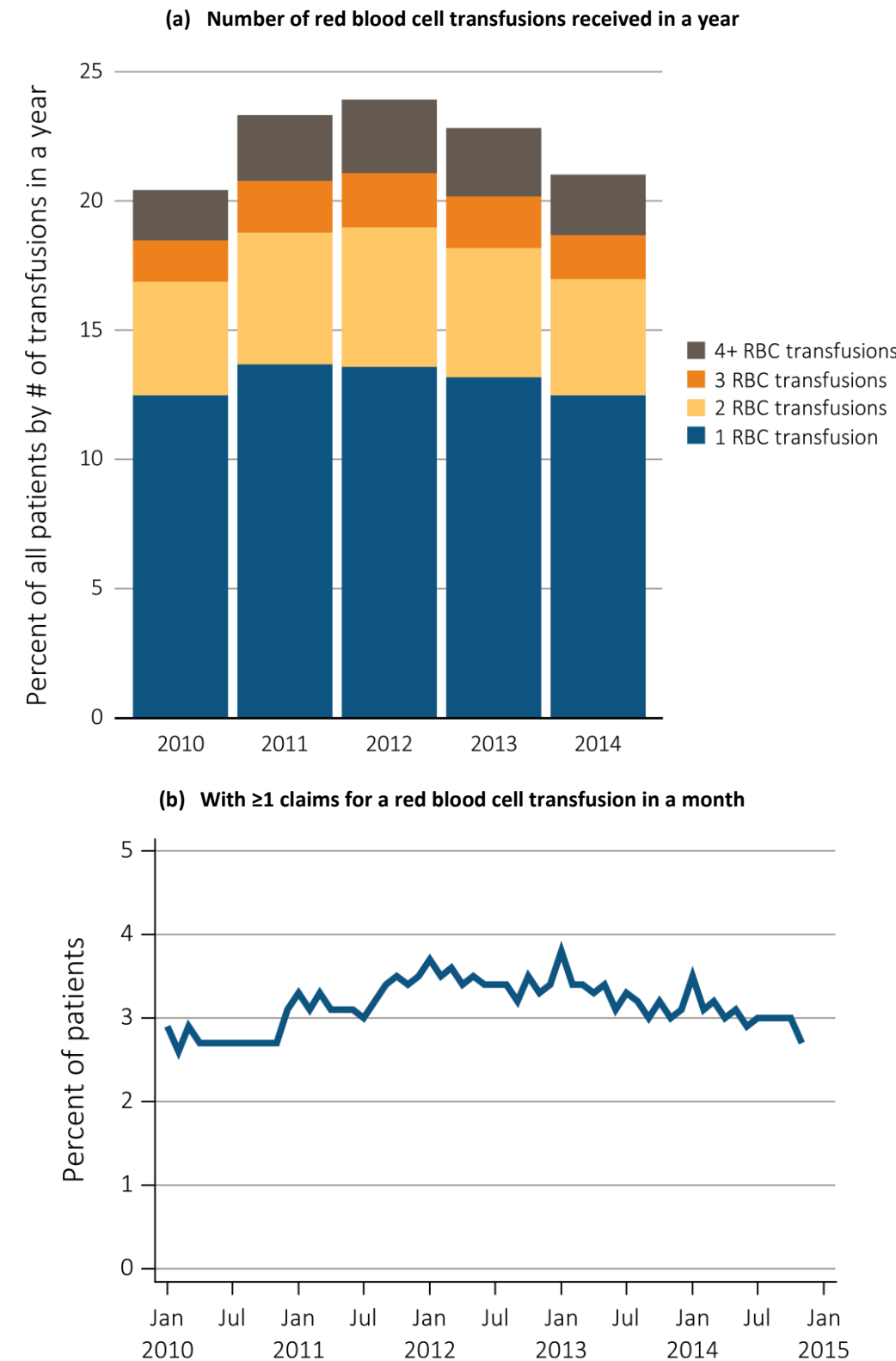
RED BLOOD CELL TRANSFUSIONS IN HEMODIALYSIS PATIENTS

The distribution of the number of red blood cell transfusions received by hemodialysis patients, by year, is shown in Figure 3.7.a, from 2010 through 2014, based on CMS claims data. The results shown are for all adults (≥ 18 years old) receiving at least one hemodialysis treatment during a given year, and represent the entire hemodialysis patient population. However, because some individuals did not receive hemodialysis therapy for the entire year, these results should be interpreted cautiously. The results indicate that 20.3% of hemodialysis patients received ≥ 1 red blood cell transfusion in year 2010, which increased to approximately 23.8% of patients in 2012, and decreased to 20.9% of hemodialysis patients in 2014. Across this five-year time period, typically 13%-14% of patients received one red blood cell transfusion per year, 4%-5% received two red blood cell transfusions per year, 1.6%-2.1% received 3 transfusions per year, and 2%-3% received ≥ 4 red blood cell transfusions per

year. Sensitivity analyses demonstrated that the percentage of hemodialysis patients receiving ≥ 1 red blood cell transfusion in a year was slightly higher when including any patient who received at least one hemodialysis treatment during the year, compared to analyses of patients who underwent hemodialysis for at least 30, 90, or 180 days within the indicated year.

Trends in the percentage of hemodialysis patients with ≥ 1 red blood cell transfusions within a month, from 2010-2014, are shown in Figure 3.7.b. Overall, the percent of hemodialysis patients receiving ≥ 1 red blood cell transfusions in a month has gradually declined from 3.6% in the first quarter of 2012 to 3.0% by the third quarter of 2014. From January to November 2014, on average, 3.1% of White patients had ≥ 1 red blood cell transfusions in a month compared to 3.0% of Black patients and 2.5% of patients of Other/Unknown race. Note that since these differences were small, only the overall trend line is shown in Figure 3.7.b.

vol 2 Figure 3.7 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, from Medicare claims data, 2010-2014



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. Abbreviation: RBC, red blood cell.

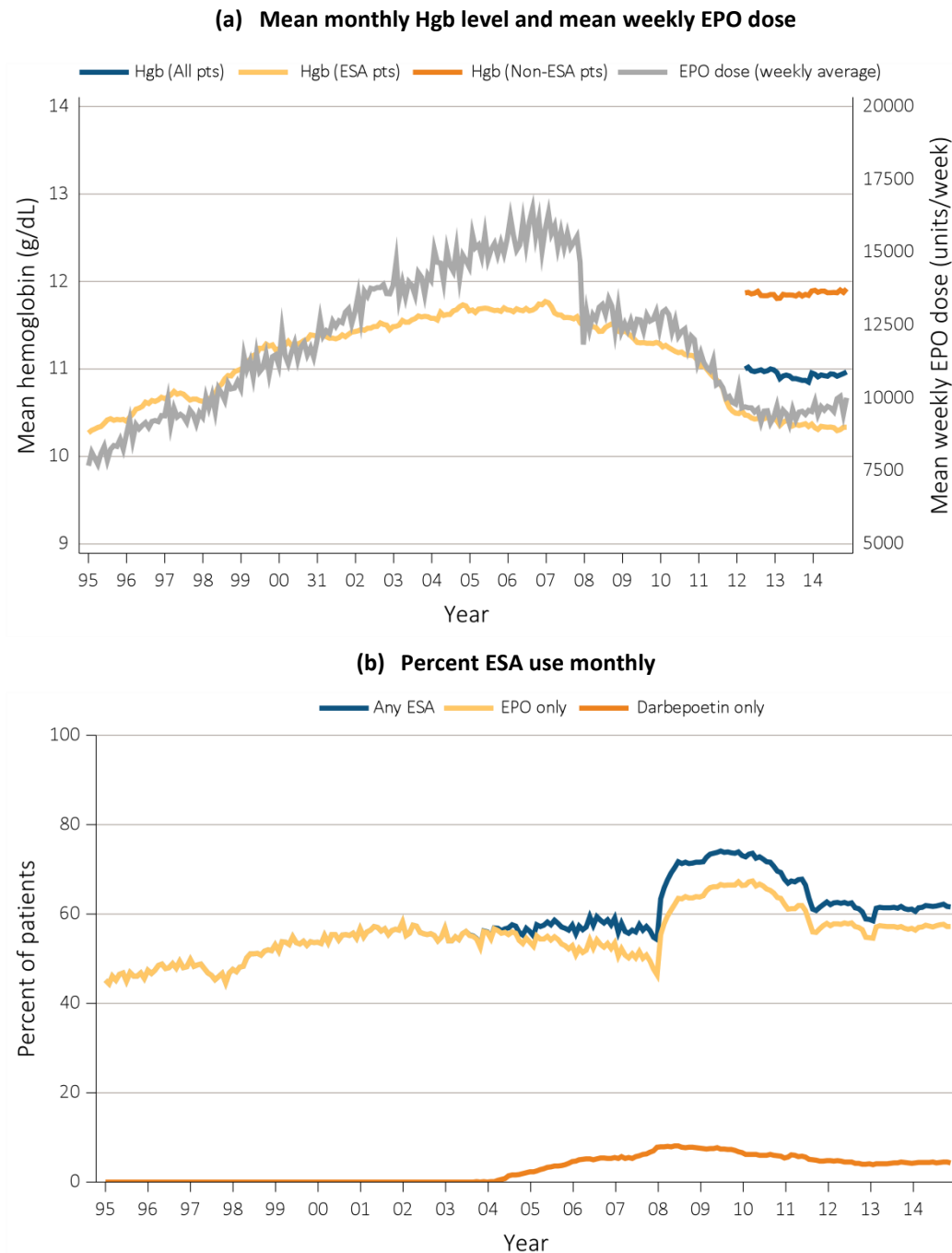
HGB LEVELS, ESA USE, AND EPO DOSE IN PERITONEAL DIALYSIS PATIENTS

Claims data indicate that mean Hgb levels have declined substantially in ESA-treated peritoneal dialysis patients since peaking near 11.8 g/dL in January 2007 (Figure 3.8.a). During 2011, the mean Hgb level for ESA-treated peritoneal dialysis patients declined 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 for ESA-treated hemodialysis patients during 2011. Since then, Hgb levels have continued to decline to a mean monthly Hgb of 10.3 g/dL in 2014 among ESA-treated peritoneal dialysis patients on dialysis ≥ 90 days. In contrast, mean monthly Hgb values of 10.9 g/dL were seen for *all* peritoneal dialysis patients on dialysis ≥ 90 days and 11.9 g/dL for non-ESA treated patients in 2014. Similarly, analyses of CROWNWeb data have indicated a similar mean Hgb level of 11.0 g/dL for *all* peritoneal dialysis patients on December 31, 2014.

The percentage of peritoneal dialysis patients on dialysis ≥ 90 days with an ESA claim during any single

month was stable at 61%-62%% during 2014 (Figure 3.8.b). In most months of 2014, approximately 57% of peritoneal dialysis patients on dialysis ≥ 90 days received EPO and 4% received darbepoetin. Mean weekly EPO dose (averaged over a month) in peritoneal dialysis patients declined approximately 24% from December 2008 to December 2014 (Figure 3.8.a). Mean weekly EPO dose was on average 2.7% higher in 2014 than in 2013 among peritoneal dialysis patients on dialysis ≥ 90 days. The mean weekly EPO dose (averaged over a month) was relatively stable throughout 2014. The mean EPO dose for peritoneal dialysis patients on dialysis ≥ 90 days, when calculated for the prevalent cross-section of these patients in each month of 2014, and then averaged across the 12 months in 2014, indicated an average weekly EPO dose of $9,716 \pm 63$ units/week in 2014. The rapid, large decline in mean weekly EPO dose (Figure 3.8.a) and rise in percent ESA use seen at the start of 2008 (Figure 3.8.b) is under further investigation since this change also coincides with a change in the reporting codes for EPO-related claims submission at that time.

vol 2 Figure 3.8 Anemia measures among adult peritoneal dialysis patients on dialysis ≥ 90 days: (a) mean monthly Hgb level and mean weekly EPO dose (averaged over a month), and (b) percent ESA use monthly, Medicare claims, 1995-2014

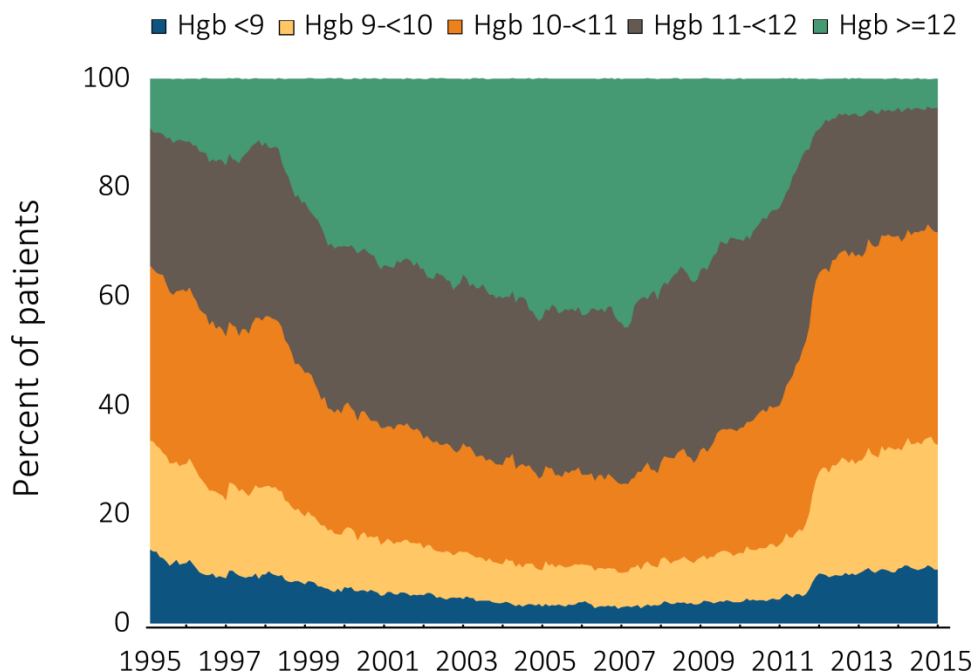


Data Source: Special analyses, USRDS ESRD Database. (a) Mean monthly Hgb level among ESA-treated adult peritoneal dialysis patients on dialysis ≥ 90 days (1995 through 2014) or mean monthly Hgb level among all adult peritoneal patients (April 2012 to December 2014 only) who, within the given month had a Hgb claim (only the first reported Hgb value in a month was used) and were on dialysis ≥ 90 days; analyses were restricted to patients ≥ 18 years old at the start of the month. Mean weekly EPO (epoetin alfa) dose is shown for peritoneal patients within a given month who had an EPO claim, were on dialysis ≥ 90 days, and were ≥ 18 years old at the start of the month. EPO dose is expressed as mean EPO units per week averaged over all EPO claims within a given month. (b) Monthly ESA use in all peritoneal dialysis patients who were ≥ 18 years old at the start of the month and were on dialysis ≥ 90 days. “EPO only” use is defined as receiving EPO but not darbepoetin; “Darbepoetin only” use is defined as receiving darbepoetin but not EPO. “Any ESA” use is defined as receiving either or both EPO and Darbepoetin. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2014, a large shift occurred in the percentage of ESA-treated adult peritoneal dialysis patients in the highest versus lowest Hgb concentration categories (Figure 3.9). Among ESA-treated patients on dialysis ≥ 90 days, the percentage with Hgb < 10 g/dL increased from 11% in 2007 to 33% in 2014, while the percentage with Hgb ≥ 12 g/dL

declined from 41.4% in 2007 to 5.5% in 2014. Among all (both ESA treated and non-ESA treated) peritoneal dialysis patients on dialysis ≥ 90 days in December 2014, 7.2% had Hgb < 9 g/dL, 16.1% had Hgb of 9 to < 10 g/dL, 54.6% had Hgb between 10-12 g/dL, and 22.1% had Hgb ≥ 12 g/dL.

vol 2 Figure 3.9 Distribution of monthly Hgb (g/dL) levels in ESA-treated adult (≥ 18 years old) peritoneal dialysis patients on dialysis ≥ 90 days, Medicare claims, 1995-2014



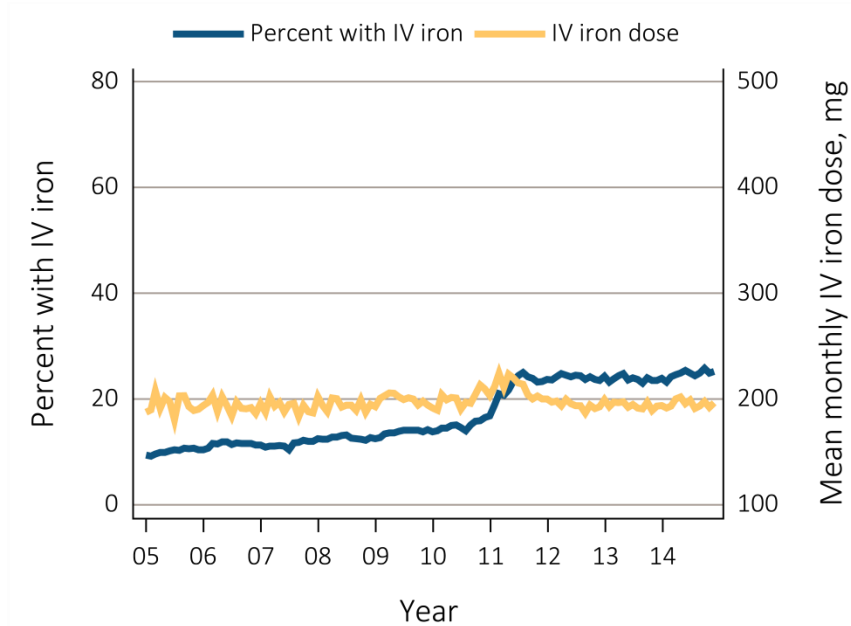
Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥ 90 days and ≥ 18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents;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

IV IRON USE, IV IRON DOSE, AND MEASURES OF IRON STORES IN PERITONEAL DIALYSIS PATIENTS

Trends in IV iron use are shown from 2005 through 2014 for peritoneal dialysis patients (Figure 3.10). 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 PPS for dialysis services in January 2011. As of the final quarter of 2014, IV iron use among peritoneal dialysis patients on dialysis ≥ 90 days has remained higher at 25.3%.

The mean monthly IV iron dose per year steadily rose from 194 mg in 2005 to 211 mg in 2011. However, coincident with the 2011 implementation of the new CMS Prospective Payment System, IV iron doses have declined to an average mean monthly IV iron dose of 194-196 mg in years 2012-2014. Thus, since 2011, IV iron use in the United States has increased, while the average monthly IV iron dose among patients given iron has declined among peritoneal dialysis patients on dialysis ≥ 90 days.

vol 2 Figure 3.10 Monthly IV iron use and mean monthly IV iron dose in adult peritoneal dialysis patients on dialysis ≥ 90 days, Medicare claims, 2005-2014



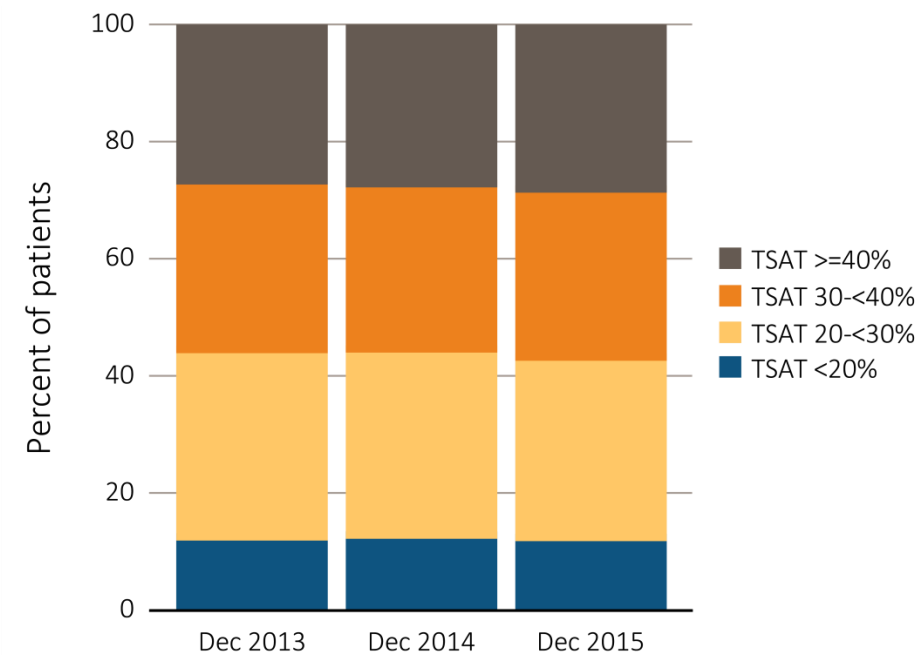
Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis ≥ 90 days and ≥ 18 years old at the start of the given month. Mean IV iron dose was calculated as the average number of mg of IV iron given to all such patients during a month, among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

As mentioned previously, reporting of the iron store measures, transferrin saturation (TSAT) and serum ferritin, has gradually increased over time. For example, when based upon the most recent serum ferritin value reported in the prior three months, serum ferritin was reported for N=29,803 peritoneal dialysis patients in 2013 versus N=39,042 peritoneal dialysis patients in 2015. Due to the changes in facility data reporting over time, the trends noted below should be interpreted cautiously.

Across the three end-of-year cross-sections shown in Figure 3.11 for TSAT and in Figure 3.12 for ferritin, the distribution of TSAT and serum ferritin levels

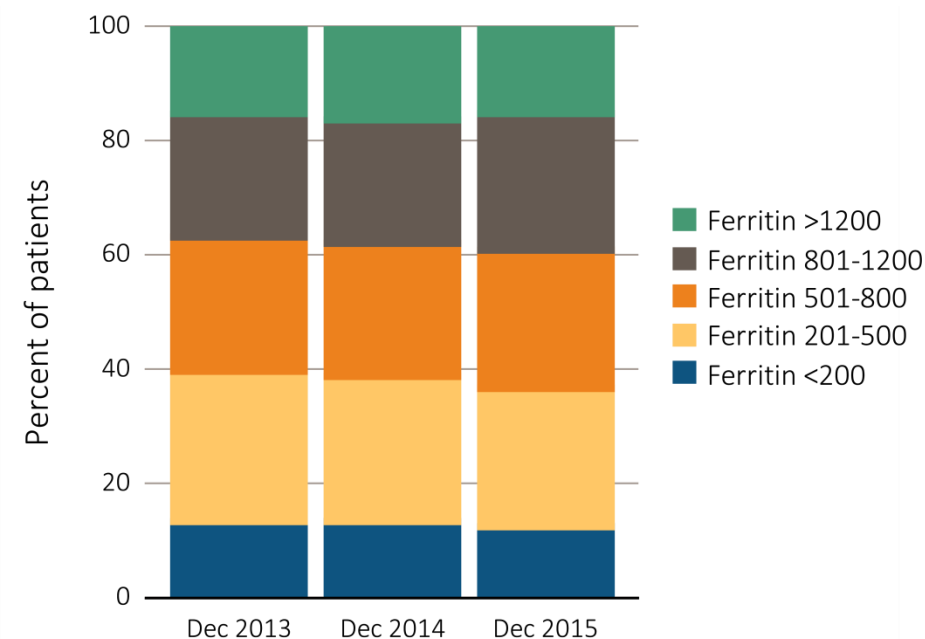
among peritoneal dialysis patients on dialysis ≥ 90 days did not differ appreciably. Averaged across the three years, 12.6% of patients had a TSAT $< 20\%$, with 31.5%, 28.6%, and 27.3% of patients having TSAT levels of 20% to $< 30\%$, 30% to $< 40\%$, and $\geq 40\%$, respectively. Across the 2013-2015 time period, on average, 13.0% of patients had a serum ferritin ≤ 200 ng/mL, with 25.3%, 23.7%, 22.4%, and 15.7% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and > 1200 ng/mL, respectively. The mean serum ferritin level slightly increased from 718 to 735 ng/mL during the December 2013 to December 2015 cross-section.

vol 2 Figure 3.11 Distribution of TSAT levels (%) in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. 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 December 1 of that year, and who were alive through December 31 of that year. Abbreviations: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network; TSAT, transferrin saturation.

vol 2 Figure 3.12 Distribution of the most recent serum ferritin (ng/mL) level taken between October and December in adult peritoneal dialysis patients on dialysis for at least 90 days, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. 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 December 1 of that year, and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

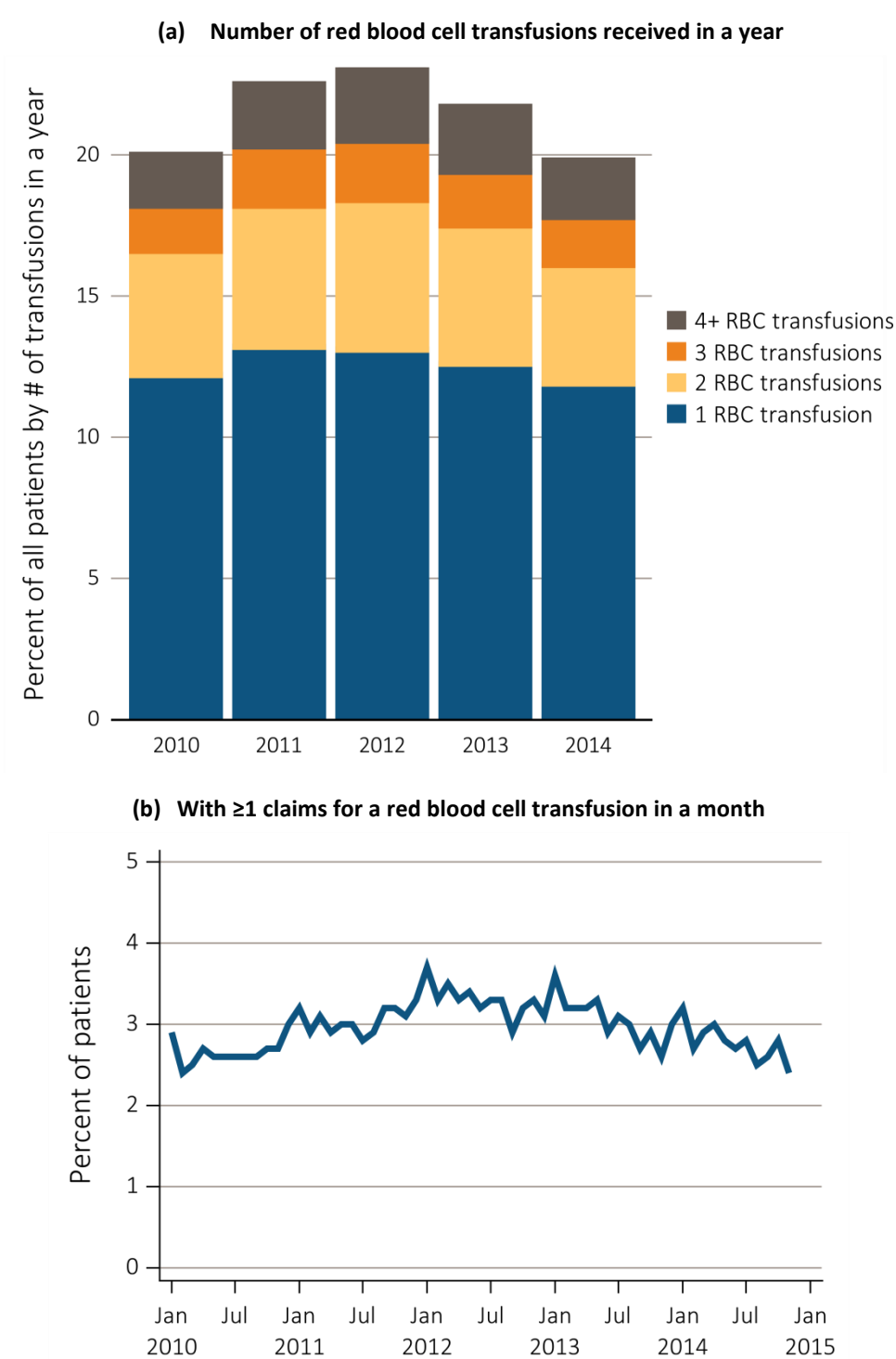
RED BLOOD CELL TRANSFUSIONS IN PERITONEAL DIALYSIS PATIENTS

The distribution of the number of red blood cell transfusions received by peritoneal dialysis patients, by year, is shown in Figure 3.13.a, during 2010 through 2014. The results shown are for all adults (≥ 18 years old) receiving at least one peritoneal dialysis treatment during a given year. However, because some individuals did not receive peritoneal therapy for the entire year, these results should be interpreted cautiously. The results indicate that 20.0% of peritoneal dialysis patients received ≥ 1 red blood cell transfusions in 2010, which increased to approximately 23% of patients in 2011 and 2012, 21.7% in 2013, and declined to 19.8% of peritoneal dialysis patients in 2014. Across this five-year time period, typically 12%-13% of peritoneal dialysis patients received 1 red blood

cell transfusion per year, 4%-5% received 2 red blood cell transfusions per year, 2% received 3 transfusions per year, and 2%-3% received ≥ 4 red blood cell transfusions per year.

Trends in the percentage of peritoneal dialysis patients with one or more red blood cell transfusions within a month, during 2010-2014, are shown in Figure 3.13.b. Overall the percent of peritoneal dialysis patients receiving ≥ 1 red blood cell transfusions in a month has gradually declined from 3.5% in the first quarter of 2012 to 2.6% by the third quarter of 2014. From January to November 2014, on average, 2.7% of White patients had ≥ 1 red blood cell transfusions in a month compared to 3.0% of Black patients and 2.4% of patients of Other/Unknown race. Note that since these differences were small, only the overall trend line is shown in Figure 3.13.b.

vol 2 Figure 3.13 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, 2010-2014



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. Abbreviation: RBC, red blood cell.

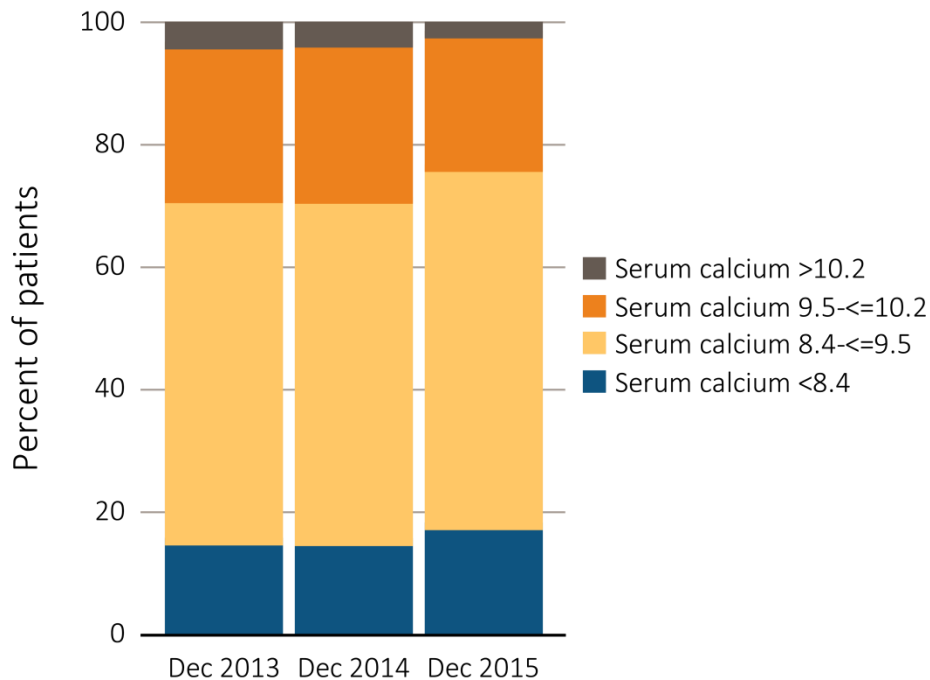
Mineral and Bone Disorder

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, which is a major cause 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, the possibility of inappropriate treatment should also be considered in these patients. Based on these observations, current Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines (KDIGO, 2009) suggest maintaining calcium and phosphorus levels in the laboratory reference range among patients on chronic dialysis.

CALCIUM

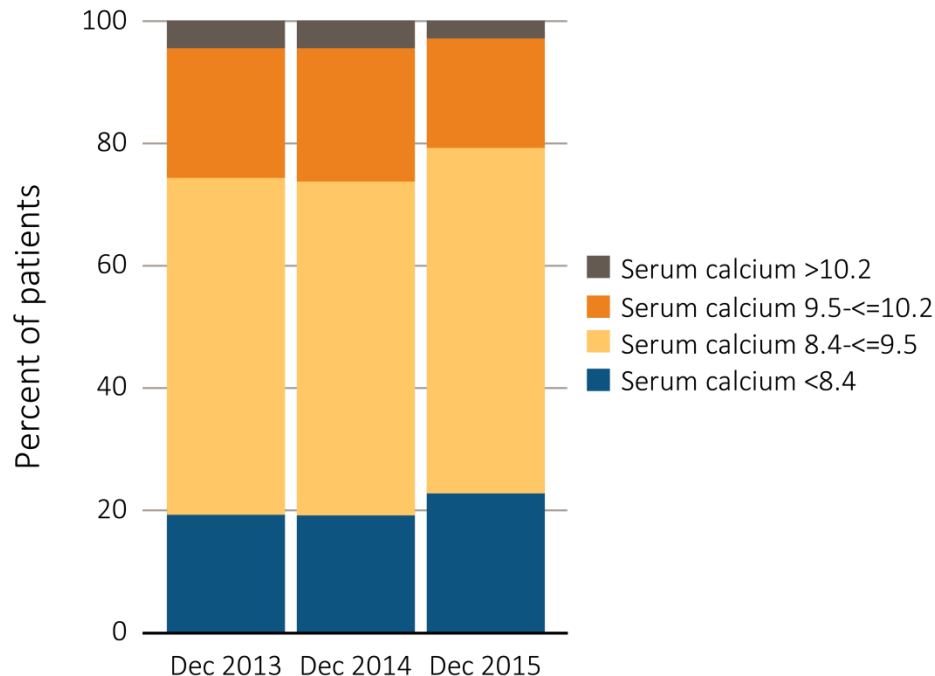
The distributions of calcium levels (based on the value in the month of December for the calendar year) among adult hemodialysis and peritoneal dialysis patients are shown in Figures 3.14 and 3.15. Between 2013 and 2015, no substantial change in calcium distribution was observed. The majority of patients (hemodialysis: 58.5%, peritoneal dialysis: 56.5%) in 2015 had calcium levels within the usual normal reference range (8.4-9.5 mg/dL), while a very small percentage (hemodialysis: 1.9%, peritoneal dialysis: 2.2%) had 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 prevalence of very low calcium levels (<8.4 mg/dL) was much higher in patients on peritoneal dialysis vs. hemodialysis (23.4% vs 17.7% in December 2015), likely due in large part to differences in dialytic treatment and serum albumin levels.

vol 2 Figure 3.14 Distribution of serum calcium levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. 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 December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 3.15 Distribution of serum calcium levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2013, 2014, and 2015



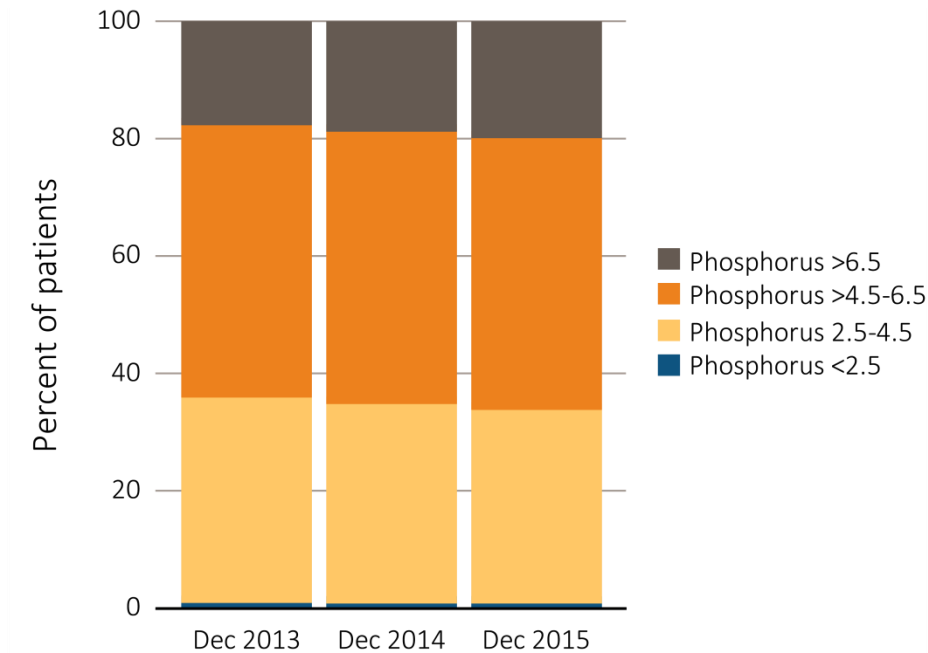
Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2013, 2014, and 2015. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥ 18 years old as of December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

PHOSPHORUS

The distributions of serum phosphorus levels among adult hemodialysis and peritoneal dialysis patients are shown in Figures 3.16 and 3.17. Between 2013 and 2015, a slight increase in mean serum phosphorus was observed both in hemodialysis and peritoneal dialysis patients (hemodialysis: from 5.2 to 5.3 mg/dL; peritoneal dialysis: from 5.3 to 5.5 mg/dL). KDIGO guidelines recommend maintaining phosphorus levels within the laboratory reference range (typically between 2.5 and 4.5 mg/dL). Among hemodialysis patients in December 2015,

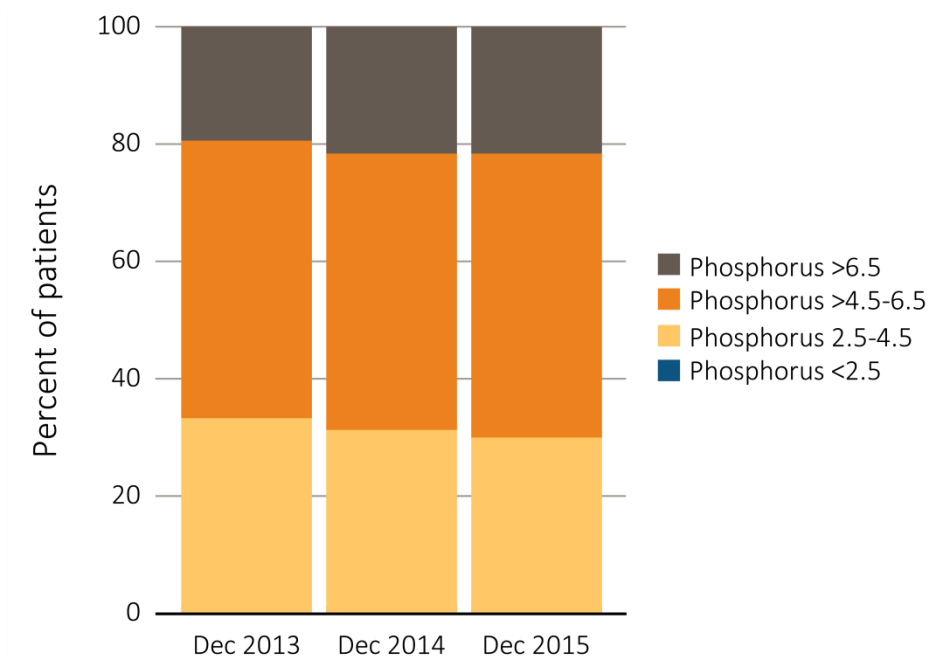
approximately two-thirds (65.5%) had serum phosphorus >4.5 mg/dL. This percentage was even higher among patients on peritoneal dialysis (69.4%), indicating a clear opportunity for improvement. Prior studies have shown that patients having low serum phosphorus levels (<2.5 mg/dL) have elevated mortality risk and have a high likelihood of malnutrition. In CROWNWeb data, in cross-sections in 2013 to 2015, a small percentage of patients had serum phosphorus levels <2.5 mg/dL (1.4%-1.5% of hemodialysis patients and 0.6%-0.7% of peritoneal dialysis patients).

vol 2 Figure 3.16 Distribution of serum phosphorus (%) levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2013, December 2014, and December 2015. 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 December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

vol 2 Figure 3.17 Distribution of serum phosphorus (%) levels in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWEB data, December 2013, 2014, and 2015



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2013, December 2014, and December 2015. 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 December 1 of that year and who were alive through December 31 of that year. Abbreviation: CROWNWeb, Consolidated Renal Operations in a Web-Enabled Network.

Preventive Care

DIABETES MELLITUS

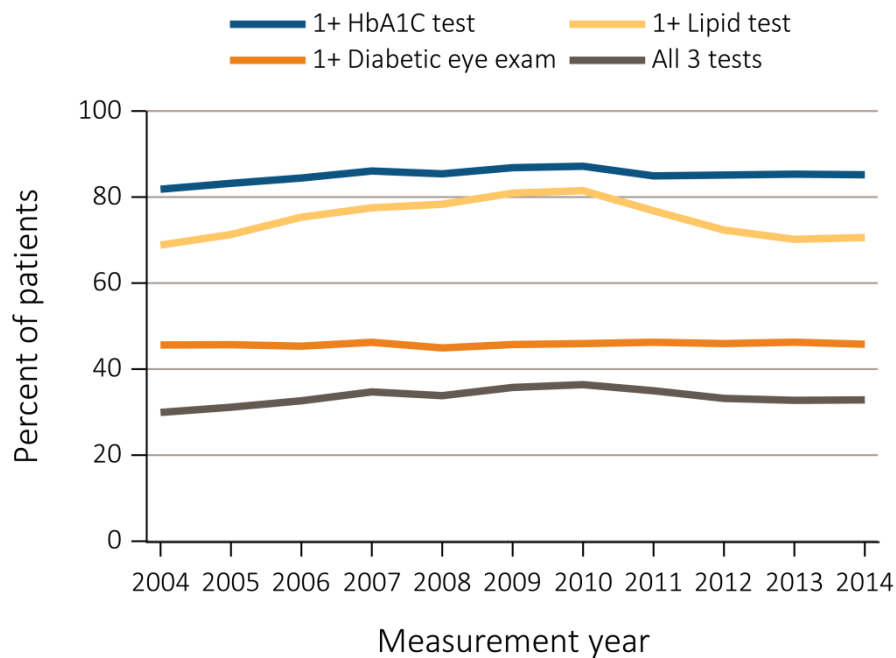
Recommendations for glycemic and lipid monitoring, treatment, and target levels in diabetic patients with ESRD are controversial. The role of regular dilated eye exams and timely treatment in preventing vision loss is, however, well-established.

From 2003 to 2010, Medicare claims show a steady increase in the percentage of ESRD patients with diabetes receiving at least one glycosylated hemoglobin (HbA_{1c}) test and at least one lipid test per year (87.2% with at least one HbA_{1c} test and 81.5% with at least one lipid test in 2009) (Figure 3.18). The National Committee for Quality Assurance Comprehensive Diabetes Care data also show an increase in testing over this time period in the privately insured population with diabetes (89% with at least one HbA_{1c} test and 85% with at least one lipid test in 2009) and in the Medicare population with diabetes (90% with at least one HbA_{1c} test and 87% with at least one lipid test in 2009) compared to the data presented in this report (National Committee for Quality Assurance, 2010). In 2011, there was a slight decrease in the percentage of patients with diabetes receiving at least one HbA_{1c} test per year and a more substantial decrease in the percentage of patients

receiving at least one lipid test per year, though rates of testing have plateaued in more recent years (Figure 3.18). The decrease in HbA_{1c} testing may reflect an increasing awareness of the limitations of HbA_{1c} as an indicator of average glycemia in patients with ESRD. National Committee for Quality Assurance Comprehensive Diabetes Care data show a leveling off, but do not demonstrate similar decreases in HbA_{1c} or low-density lipoprotein (LDL) cholesterol testing rates since 2010 in the privately insured, Medicaid, or Medicare populations with diabetes (National Committee for Quality Assurance, 2014). The reason for the apparent decrease in lipid testing rates in the Medicare ESRD population with diabetes is unclear, but may possibly be related to the publication of two reports demonstrating a lack of effect of statin therapy on fatal and nonfatal cardiovascular outcomes in patients undergoing hemodialysis (Wanner et al., 2005; Fellstrom et al., 2009).

The percentage of patients with annual dilated eye exams has remained low but constant over the past decade (approximately 46%, which is lower than the Healthy People 2020 target of 58.7%), with a similar pattern for the performance of all three tests (approximately 33% in the most recent year). There remains a substantial opportunity for quality improvement.

vol 2 Figure 3.18 Diabetes-related care among ESRD patients with diabetes mellitus aged 18-75 years, Medicare claims, 2004-2014



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 and diabetes-related care in the measurement year.

Abbreviations: ESRD, end-stage renal disease; HbA1c, glycosylated hemoglobin.

VACCINATION

Yearly influenza vaccination is recommended for all ESRD patients. Seasonal influenza vaccination is defined here more broadly than the typical October through March influenza season, and covers the period of August 1 through April 30 to account for early or later vaccinations. Based on Medicare claims data, the percentage of ESRD patients receiving influenza vaccination has slowly improved over the past decade, rising from 58.4% in the 2003-2004 season to 70.7% in the 2013-2014 season, though it appears to have plateaued over the last two seasons (Figure 3.19.a). However, it remains below the Healthy People 2020 (HP2020) target of 90%. The percentage of patients vaccinated is highest in older age groups, with only 44.0% of ESRD patients aged 0-21 years vaccinated in the 2013-2014 season (Figure 3.19.b). The percentage of patients vaccinated is similar in the most recent years across race/ethnicity, though slightly lower among Blacks at 68.6% in the 2013-2014

season (Figure 3.19.c). By modality, hemodialysis patients were vaccinated at the highest frequency (75.5% in the most current data), compared with 73.2% in peritoneal dialysis patients, and 53.9% in kidney transplant patients (Figure 3.19.d). The higher percentage of vaccination in hemodialysis patients may relate to the greater frequency of medical contact, providing more opportunities for vaccination. The percentage vaccinated may also be lower in transplant patients in part because vaccination is often delayed for several months after a new transplant due to concerns about an ineffective immune response or the possibility of triggering an acute rejection episode. The percentages vaccinated reported here may be underestimates, as they are derived from claims, which may not completely capture all vaccination events. Future analyses for the ADR will utilize CROWNWeb data, which should provide more complete information on vaccination, including status for other recommended vaccinations, such as for pneumococcus and hepatitis B.

vol 2 Figure 3.19 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/ethnicity, and (d) by modality, Medicare data, 2003-2014

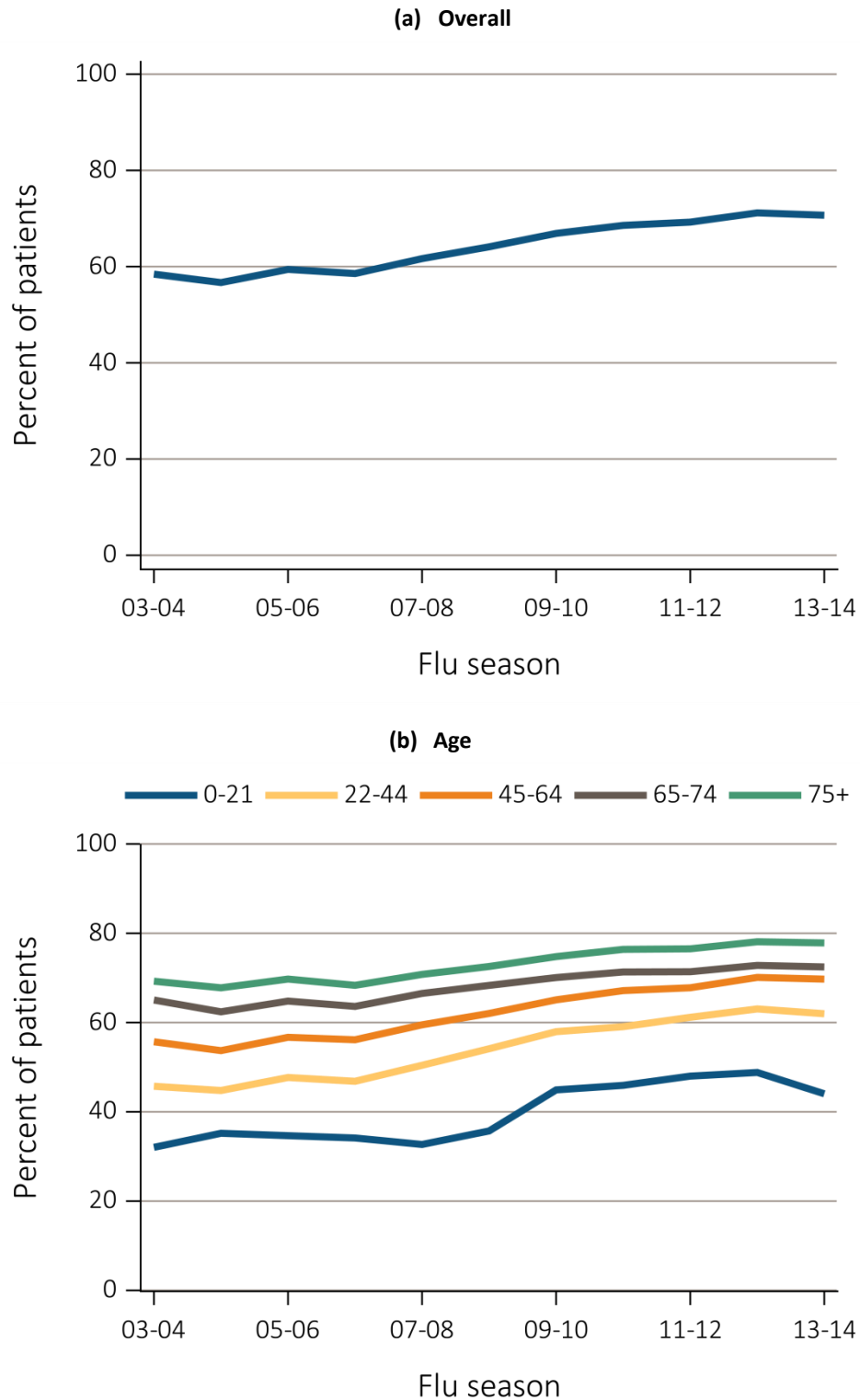
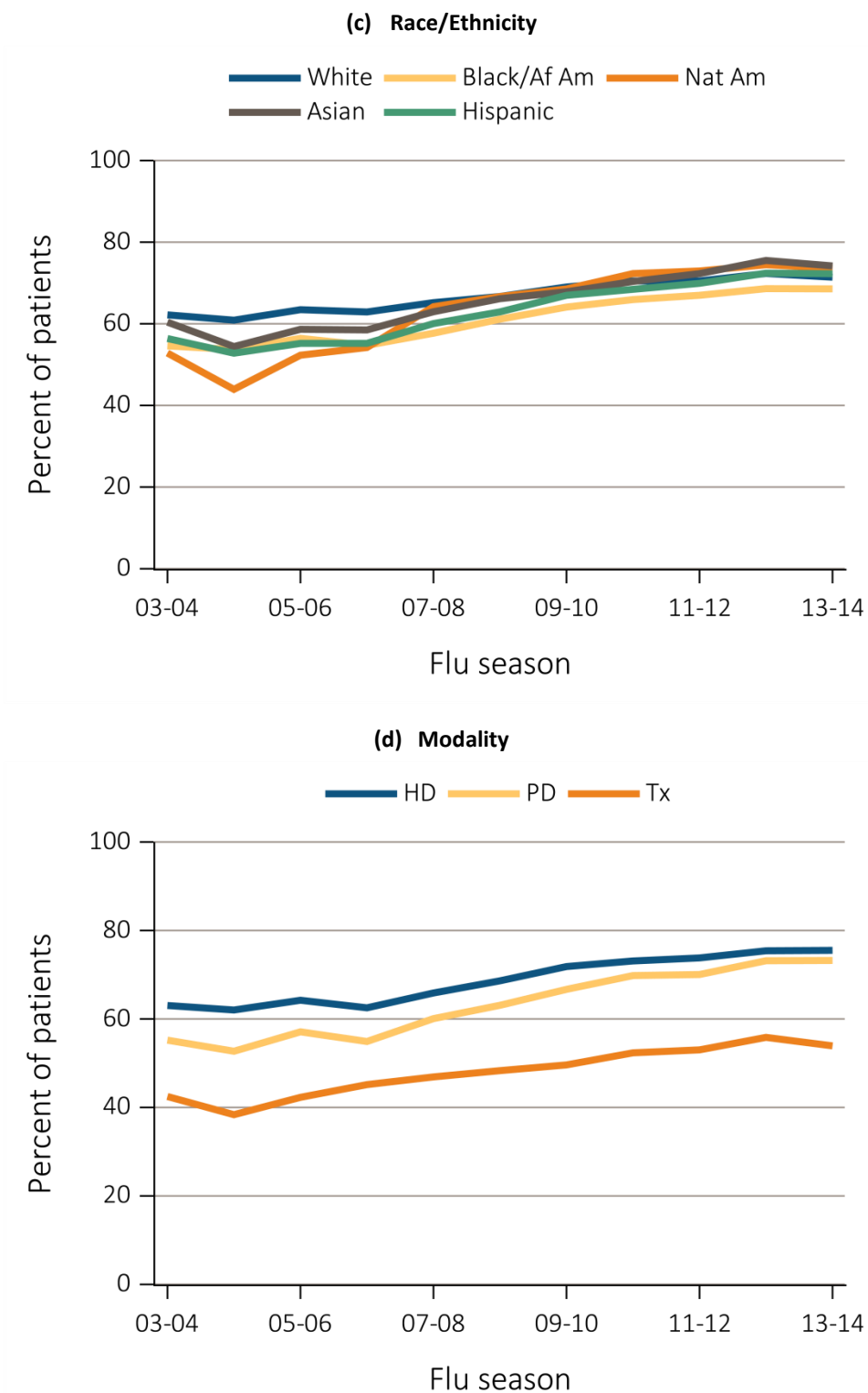


Figure 3.19 continued on next page.

vol 2 Figure 3.19 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/ethnicity, and (d) by modality, Medicare data, 2003-2014 (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. Abbreviations: Af Am, African American; ESRD, end-stage renal disease; HD, hemodialysis; Nat Am, Native American; PD, peritoneal dialysis; Tx, transplant.

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