
Chapter 3: Clinical Indicators and Preventive Care

Anemia

- The majority (65%) of hemodialysis patients in December 2014 had Hgb levels between 10-12 g/dL, while nearly 14% had Hgb \geq 12 g/dL. 6% had Hgb less than 9 g/dL while 15% had Hgb between 9-10g/dL, with the mean Hgb being 10.8g/dL.
- The majority (55%) of peritoneal dialysis patients in December 2014 had Hgb levels of 10-12 g/dL, while 21%, had Hgb \geq 12 g/dL. 7% had Hgb less than 9 g/dL while 16% had Hgb between 9-10g/dL, with the mean Hgb being 10.9g/dL.
- From December 2012 to December 2013, EPO doses declined by 5-7% in hemodialysis and peritoneal dialysis patients in the United States. In 2013, average monthly EPO doses were approximately 10,600 units/week and 9,500 units/week for hemodialysis and peritoneal dialysis patients, respectively.
- Little change was seen in IV iron use and IV iron dose from 2012 to 2013 in U.S. dialysis patients.
- Serum ferritin levels rose in all dialysis patients from 2012 to 2014, with 58% of hemodialysis patients and 39% of peritoneal dialysis patients having serum ferritin levels $>$ 800 ng/mL.

Mineral and Bone Disorder

- 56% of hemodialysis and 55% of peritoneal dialysis patients had calcium levels within a typical laboratory reference range (8.4-9.5 mg/dL); 4% had calcium levels $>$ 10.2 mg/dL, whereas 15% of hemodialysis patients and 21% of peritoneal dialysis patients had calcium levels $<$ 8.4 mg/dL.
- In December 2014, 37% of hemodialysis patients and 42% of peritoneal dialysis patients had serum phosphorus levels $>$ 5.5 mg/dL.

Preventive Care

- In 2013, only 33% 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 37% in 2010.
- 71% of patients received an influenza vaccination in the 2012-2013 flu season, which is still below the Healthy People 2020 (HP2020) target of 90%. However, it represents a steady increase from 58% in the 2003-2004 season.

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 been undergoing a transition from paper-based data entry to web-based or electronic data entry, 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 though the system is still evolving and not all data are fully captured. CMS ESRD data for the Annual Data Report (ADR) have traditionally relied on Medicare claims, but last year, for the first

time, CROWNWeb data were used for analyses in this chapter pertaining to dialysis adequacy, vascular access among prevalent hemodialysis patients, and selected anemia measures. This year, CROWNWeb data are used in this chapter for analyses on dialysis adequacy, bone and mineral disorders, and selected anemia measures. Reporting on vascular access has been moved to a new chapter this year: Chapter 4: Vascular Access.

ANALYTICAL METHODS

See the ESRD Analytical Methods chapter for an explanation of analytical methods used to generate the figures and tables in this chapter.

Clinical Indicators

In Figure 3.1, we present CROWNWeb data from December 2014 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 97% 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 87% (Figure 3.1.a).

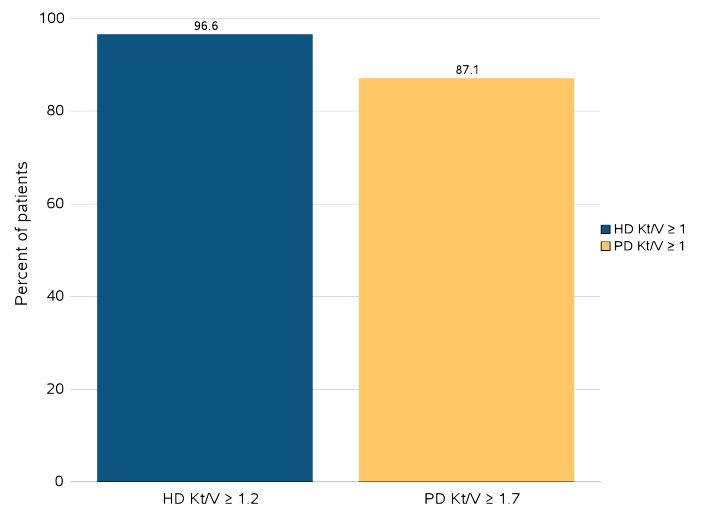
Views on anemia treatment with srythropoiesis-stimulating agents (ESAs) have evolved in recent years, as safety concerns have emerged from clinical trials about maintaining Hgb levels greater than 11.5 to 13g/dL, with guidelines recommending Hgb correction to less than 11.5g/dL. This has resulted in 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 (65%) have Hgb levels in the range of 10-12 g/dL, with 13.5% having Hgb ≥ 12 g/dL. The pattern is similar with peritoneal dialysis patients, though a somewhat higher percentage (21.4%) have Hgb ≥ 12 g/dL. Later in this chapter, Medicare claims (updated through 2013) 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 with serum calcium levels >10.2 mg/dL as of December 2014, calculated as a three-month rolling average, similar to methods utilized by

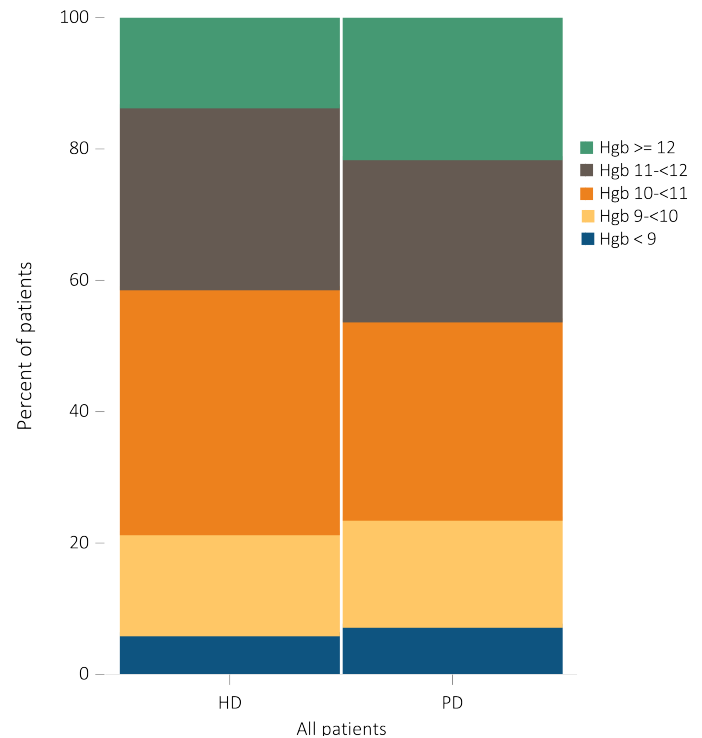
the QIP. The rationale for this measure is to encourage avoidance of hypercalcemia given its associations with vascular calcifications and cardiovascular events. Later in the chapter we present additional CROWNWeb data on trends in serum calcium and phosphorus levels.

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) percentage distribution of achieved mean Hgb among prevalent hemodialysis and peritoneal dialysis patients; and (c) percentage of patients with serum calcium >10.2 mg/dL by modality, CROWNWeb data, December 2014

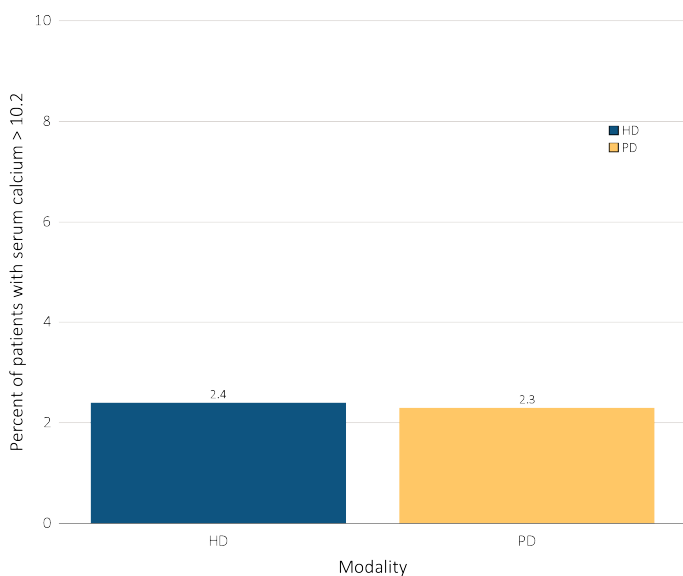
(a) Percentage of prevalent hemodialysis and peritoneal dialysis patients meeting clinical care guidelines for dialysis adequacy by modality



(b) percentage distribution of achieved mean Hgb among prevalent hemodialysis and peritoneal dialysis patients



(c) Percentage of 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 2014, restricted to patients as follows: Panel a: Dialysis patients initiating treatment for ESRD at least 1 year prior to December 1, 2014, and who were alive through December 31, 2014. Panel b: Dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2014, who were ≥ 18 years old as of December 1, 2014, and who were alive through December 31, 2014. Panel c: Hemodialysis and peritoneal dialysis patients initiating treatment for ESRD at least 90 days prior to December 1, 2014, who were ≥ 18 years old as of December 1, 2014, and who were alive through December 31, 2014. Abbreviations: ESRD, end-stage renal disease; HD, hemodialysis; Hgb, hemoglobin; Kt/V, see Glossary; PD, peritoneal dialysis.

Anemia Treatment by Modality

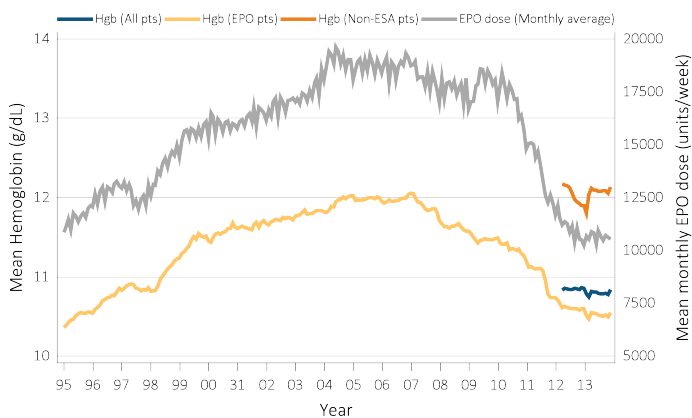
In this section, long-term trends in Hgb levels, ESA use, erythropoietin (EPO) dose, intravenous (IV) iron use, IV iron dose, levels of iron stores, and red blood cell transfusion rates are described through the year 2013 by dialysis modality in CMS claims data. New additions to this section in 2015 include the first description of serum ferritin and transferrin saturation (TSAT) levels as a result of the availability of these data from CROWNWeb for years 2012 to 2014. Furthermore, monthly mean IV iron doses are now provided for years 2005 to 2013 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). 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 decline to a mean monthly Hgb of 10.5 g/dL among ESA-treated hemodialysis patients in 2013. In contrast, mean monthly Hgb values in 2013 were 10.8 g/dL for *all* hemodialysis patients and 12.0 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 on December 31, 2013. Mean Hgb levels appeared to have stabilized in 2013, with only small changes in mean values across most months of 2013.

Typically, 79-80% of hemodialysis patients had a claim for ESA use during any single month in 2013. Among hemodialysis patients with an ESA claim in 2013, 96.5% of patients received EPO and 3.5% received darbepoetin. Between 2007 and 2013, mean monthly EPO doses (averaged over a month) have declined 42% in hemodialysis patients, with a nearly 5% decline from 2012 to 2013 (Figure 3.2). Throughout 2013, the mean monthly EPO dose (averaged over a month) was relatively stable, with a typical mean monthly EPO dose of 10,620 +/- 17.9 units/week.

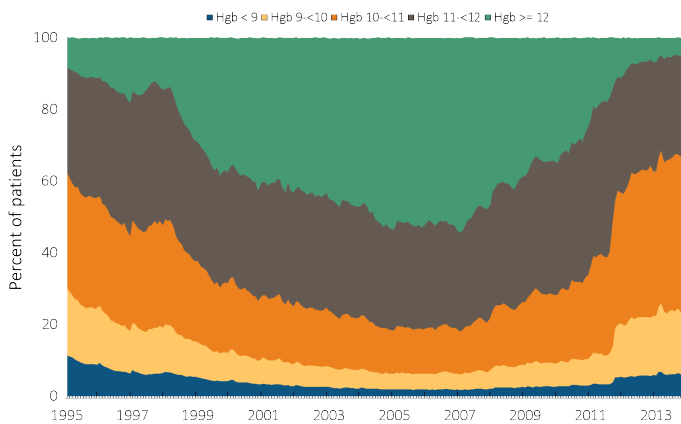
vol 2 Figure 3.2 Mean monthly Hgb level and mean monthly EPO dose (expressed as units/week) in adult hemodialysis patients on dialysis ≥ 90 days, Medicare claims, 1995-2013



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among ESA-treated hemodialysis patients within a given month (1995 through 2013) or all hemodialysis patients (April 2012 to December 2013 only) who, within the given month, had a Hgb claim, were on dialysis ≥ 90 days, and were ≥ 18 years old at the start of the month. Mean monthly 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. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

Between 2007 and 2013, a large shift was seen in the percentage of ESA-treated 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 24% in 2013 among ESA-treated patients, while the percentage with Hgb ≥ 12 g/dL declined from 50% in 2007 to 5% in 2013. Among all hemodialysis patients in December 2013, 5.4% had Hgb < 9 g/dL, 14.7% had Hgb of 9.0 to < 10 g/dL, 65.3% had Hgb between 10-12g/dL, and 14.6% 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, 1995-2013



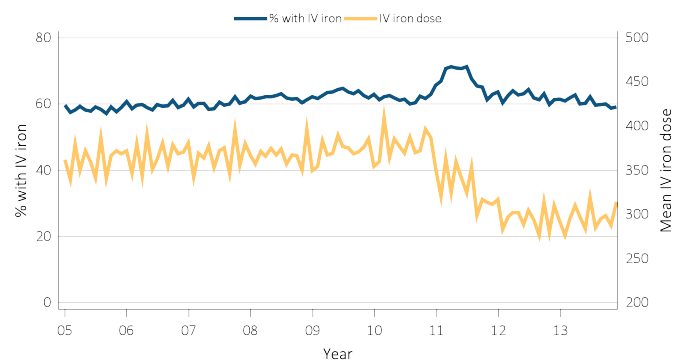
Data Source: Special analyses, USRDS ESRD Database. Distribution among hemodialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥ 90 days, and were ≥ 18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin.

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 2013 are shown in Figure 3.4. IV iron use increased sharply from 60% in August 2010 to 71% by April 2011. However, since July 2011, IV iron use has declined steadily to 59% by December 2013, essentially the pre-bundled payment level. This year for the first time, the trend in mean monthly IV iron dose is

provided for 2005 through 2013, as calculated among patients with an IV iron dose claim during a 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 new CMS Prospective Payment System, IV iron doses declined from an average mean monthly IV iron dose of 332 mg in 2011, to 297 mg in 2012, and 296 mg in 2013. 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 IV iron use and mean monthly IV iron dose in adult hemodialysis patients on dialysis ≥ 90 days, Medicare claims, 2005-2013



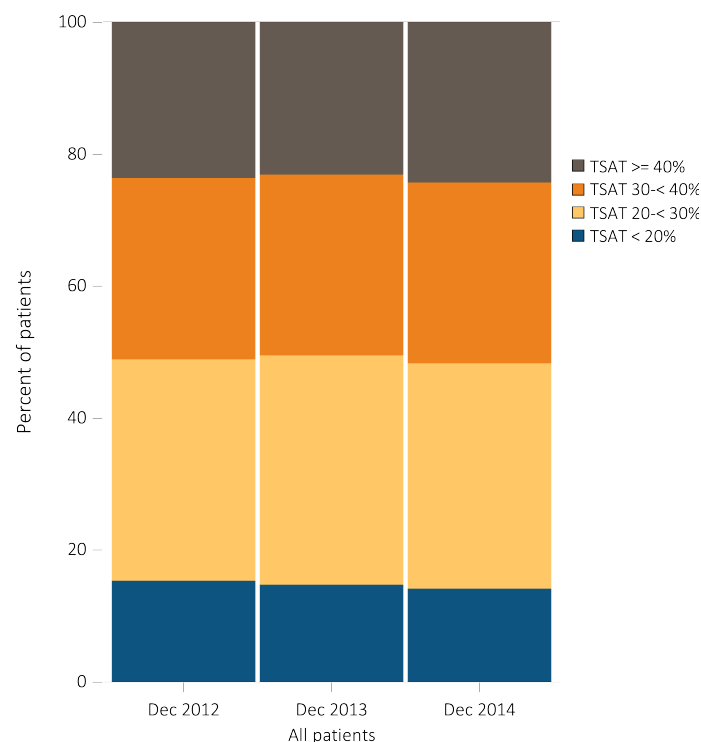
Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among hemodialysis patients on dialysis ≥ 90 days and ≥ 18 years old at the start of the given month. Mean IV iron dose was calculated as the average dose of IV iron a patient received, among patients receiving iron during the 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. This reporting has allowed, for the first time in the ADR, the presentation of distributions of TSAT and serum ferritin, for years 2012 through 2014. Reporting of these measures into CROWNWeb has 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=280,870 hemodialysis patients in 2012 versus N=375,188 hemodialysis patients in 2014. Typically, reporting of TSAT levels in hemodialysis patients was 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.

Across the three end-of-year TSAT cross-sections shown in Figure 3.5, 14.4% of patients had a TSAT $< 20\%$, with 34%, 27%, and 25% of patients having TSAT levels of 20 to $< 30\%$, 30% to $< 40\%$, and $\geq 40\%$,

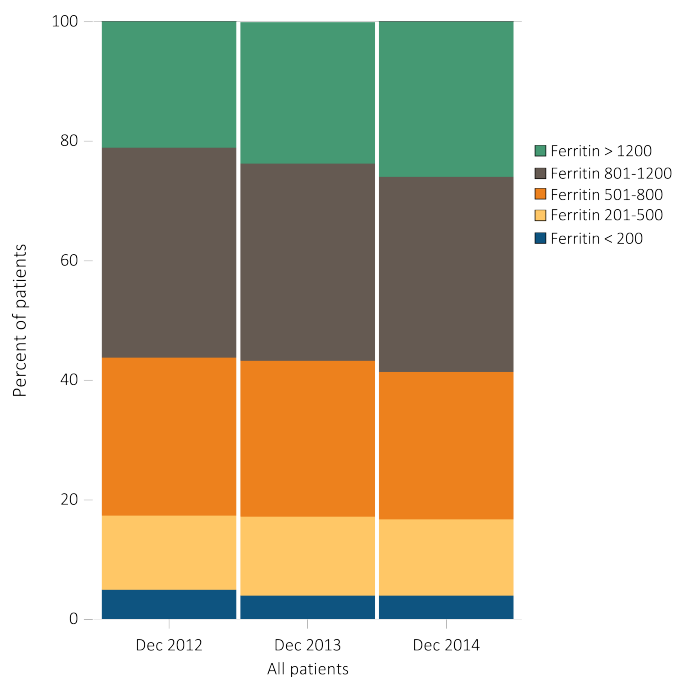
respectively. Over this three-year time period, the percentage of patients with TSAT <20% declined modestly from 15.1% to 13.8%, and the percentage of patients in the other TSAT categories remained relatively stable. Across the three end-of-year serum ferritin cross-sections shown in Figure 3.6, 4.3% of patients had serum ferritin ≤200 ng/mL, with 13%, 26%, 34%, and 24% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL, respectively. Over this three-year time period, the percentage of patients with serum ferritin >1200 ng/mL gradually increased from 21% to 26%, accompanied with small declines in the percentage of patients with serum ferritin levels of 501-800 and 801-1200 ng/mL, suggesting a shift over time toward higher serum ferritin levels. Consistent with this, the mean serum ferritin level increased from 904 to 985 ng/mL from the December 2012 to December 2014 cross-section.

vol 2 Figure 3.5 Distribution of TSAT levels (%) in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2012, 2013, and 2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2012, December 2013 and December 2014. Dialysis patients on treatment for ESRD at least 1 year 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. Abbreviation: 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 1 year, CROWNWeb data, 2012-2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2012, 2013 and 2014. Dialysis patients initiating treatment for ESRD at least 1 year 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.

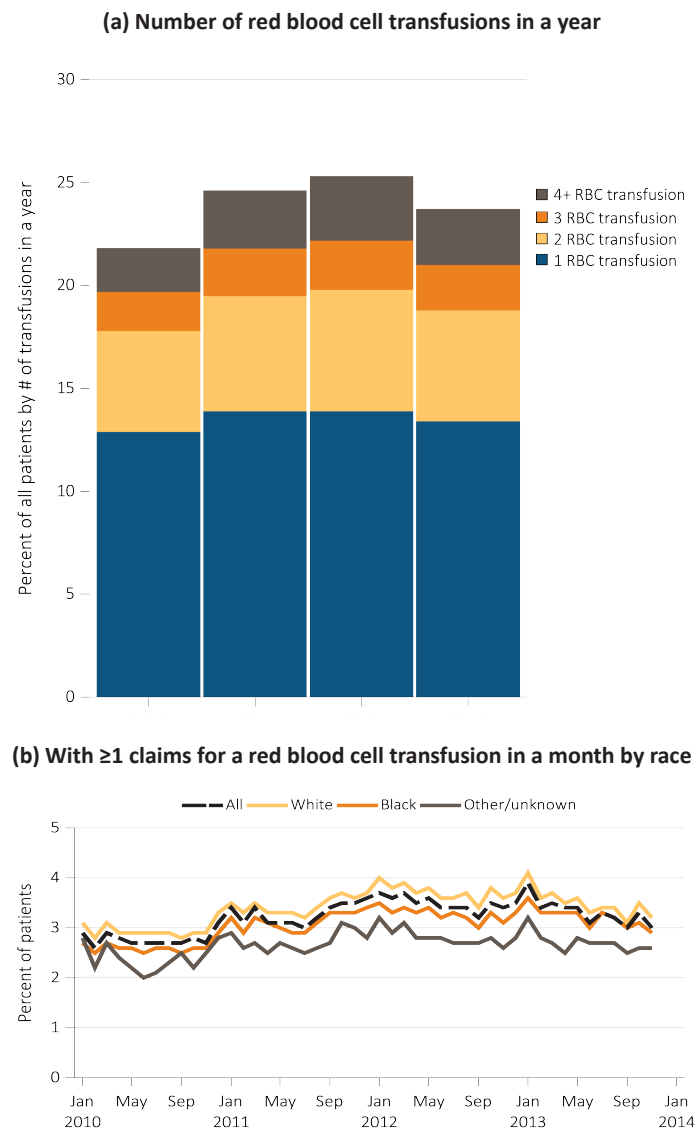
RED BLOOD CELL TRANSFUSIONS IN HEMODIALYSIS PATIENTS

The distribution of the number of red blood cell transfusions received by hemodialysis patients, by year, is shown in Figure 3.7.a, during 2010 through 2013, 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 21.7% of hemodialysis patients received ≥1 red blood cell transfusion in year 2010, which increased to approximately 25% of patients in years 2011 and 2012, and decreased to 23.9% of hemodialysis patients in 2013. Across this four-year time period, typically 13-14% of patients received one red blood cell transfusion per year, 5-6% received two red blood cell transfusions per year, with 2.0-2.5% receiving 3 transfusions per year, and 2-3% receiving ≥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 requiring that patients receive hemodialysis for at least 30, 90, or 180 days within the indicated year for inclusion in the given analysis.

The percentage of hemodialysis patients with red blood cell transfusions within a month showed some variation by race (3.7.b). Among hemodialysis patients, from January to November 2013, on average, 3.5% of White patients had ≥ 1 red blood cell transfusions in a month compared to 3.2% of Black patients and 2.7% of patients of Other/Unknown race.

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 by race, from Medicare claims data, 2010-2013



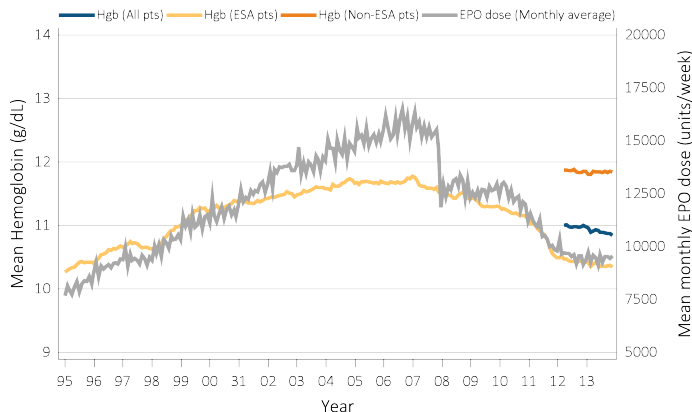
Data Source: Special analyses, USRDS ESRD Database. The percentage of hemodialysis patients ≥ 18 years old at the start of the month with ≥ 1 red blood cell transfusion claims in a given month among hemodialysis patients having a claim for at least one dialysis session during the month. Abbreviation: 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). 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, and the mean Hgb level achieved was lower than that seen for ESA-treated hemodialysis patients during 2011. Since then, Hgb levels have continued to decline to a mean monthly Hgb of 10.4 g/dL among ESA-treated peritoneal dialysis patients. In contrast, mean monthly Hgb values in 2013 of 10.9 g/dL were seen for *all* peritoneal dialysis patients and 11.8 g/dL for non-ESA treated patients. Similarly, analyses of CROWNWeb data have indicated a similar mean Hgb level of 10.9 g/dL for *all* peritoneal dialysis patients on December 31, 2013. Mean Hgb levels appear to have stabilized in 2013, with only small changes in mean values across most months of 2013.

The percentage of peritoneal dialysis patients with an ESA claim during any single month increased from 58% to 63% during 2013. Among peritoneal dialysis patients with an ESA claim in 2013, approximately 93% received EPO and 7% received darbepoetin. Mean monthly EPO dose (expressed as units per week) in peritoneal dialysis patients declined 18% from December 2010 to December 2011 (Figure 3.8). In 2012, mean monthly EPO doses declined by an additional 7%, from 9,857 units per week in December 2011 to 9,145 units per week in December 2012. Throughout 2013, the mean monthly EPO dose was relatively stable, with a typical mean monthly EPO dose of 9,453 +/- 15 units/week. The rapid, large decline in mean monthly EPO dose seen at the start of 2008 (Figure 3.8) is under further investigation since this change also coincides with a change in the reporting codes for EPO-related claims submission at that time.

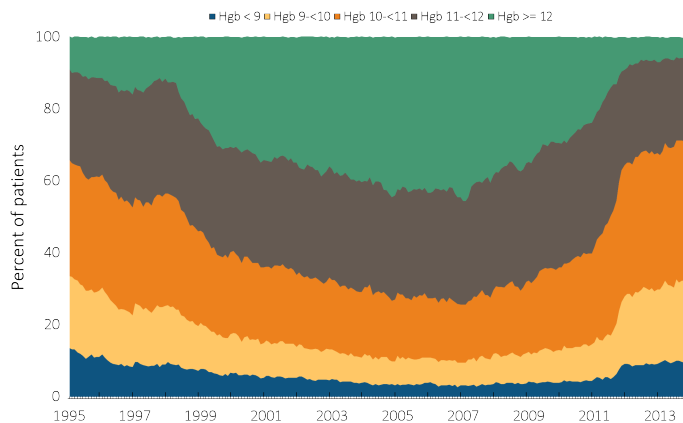
vol 2 Figure 3.8 Mean monthly Hgb level and mean monthly EPO dose (expressed as units/week) in adult peritoneal dialysis patients on dialysis ≥ 90 days, Medicare claims, 1995-2013



Data Source: Special analyses, USRDS ESRD Database. Mean monthly Hgb level among ESA-treated peritoneal dialysis patients within a given month (1995 through 2013) or all peritoneal dialysis patients (April 2012 to December 2013 only) who, within the given month, had an Hgb claim, were on dialysis ≥ 90 days, and were ≥ 18 years old at the start of the month. Mean monthly EPO (epoetin alfa) dose is shown for peritoneal dialysis 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. Abbreviations: EPO, erythropoietin; ESA, erythropoiesis-stimulating agents; Hgb, hemoglobin; Hgb (non-ESA), hemoglobin levels among patients not receiving an ESA during the month.

Between 2007 and 2013, a large shift was seen in the percentage of ESA-treated peritoneal dialysis patients in the highest versus lowest Hgb concentration categories (Figure 3.9). Among ESA-treated patients, the percentage with Hgb < 10 g/dL increased from 11% in 2007 to 32% in 2013, while the percentage with Hgb ≥ 12 g/dL declined from 41% in 2007 to 6% in 2013. Among all peritoneal dialysis patients in December 2013, 8% had Hgb < 9 g/dL, 17% had Hgb of 9.0 to < 10 g/dL, 56% had Hgb between 10-12 g/dL, and 19% 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, 1995-2013

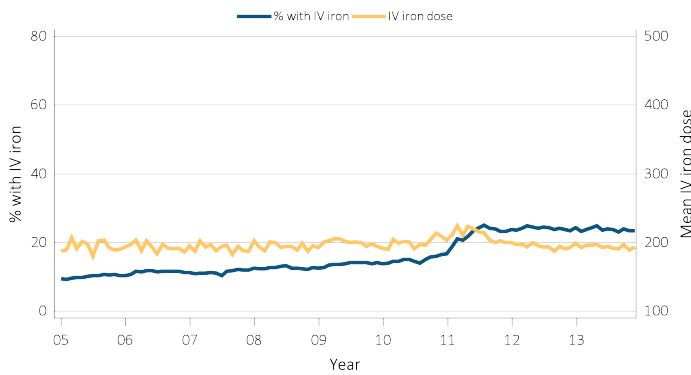


Data Source: Special analyses, USRDS ESRD Database. Distribution of Hgb levels among peritoneal dialysis patients within a given month who had claims for Hgb level and ESA use, were on dialysis ≥ 90 days, and were ≥ 18 years old at the start of the month. Abbreviations: ESA, erythropoiesis-stimulating 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 2013 for peritoneal dialysis patients (Figure 3.10). IV iron use increased sharply from 16% in November 2010 to 25% by August 2011. IV iron use has since declined slightly to 24% in December 2013. In the 2015 ADR, the trend in mean monthly IV iron dose is provided for the first time, covering the time period from 2005 through 2013, as calculated among patients with an IV iron dose claim during a month. The average of the mean monthly IV iron dose within a 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 declined to an average mean monthly IV iron dose of 195 mg in 2012. The average mean monthly IV iron dose in 2013 (194 mg) was nearly the same as that seen in 2012 (195 mg). Thus, since 2011, IV iron use has increased while the average monthly IV iron dose among patients given iron has declined in the United States among peritoneal dialysis patients.

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, 2005-2013



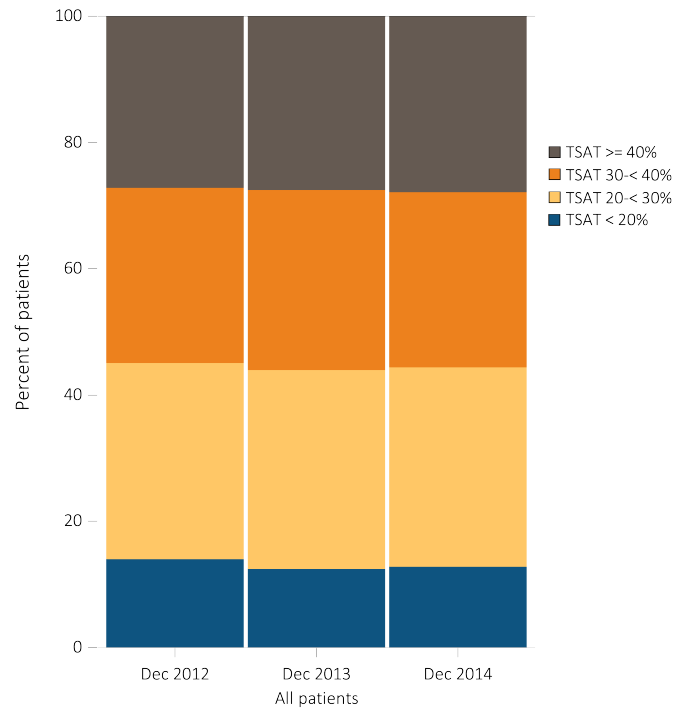
Data Source: Special analyses, USRDS ESRD Database. Monthly IV iron use is among peritoneal dialysis patients on dialysis ≥90 days and ≥18 years old at the start of the given month. Mean IV iron dose was calculated as the average doses of IV iron a patient received, among patients receiving iron during 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=19,530 peritoneal dialysis patients in 2012 versus N=30,826 peritoneal dialysis patients in 2014. Typically, reporting of TSAT levels was 2-15% lower than for serum ferritin levels in peritoneal dialysis patients. Due to the changes in reporting of data from facilities over time, the trends noted below should be interpreted cautiously.

Across the three end-of-year TSAT cross-sections shown in Figure 3.11, 13% of patients had a TSAT <20%, with 31%, 28%, and 28% of patients having TSAT levels of 20 to <30%, 30% to <40%, and ≥40%, respectively. Over this three-year time period, the percentage of patients with a TSAT <20% gradually declined from 14% to 13% whereas the percentage of patients in the other TSAT categories remained relatively stable over this time period. Across the three end-of-year serum ferritin cross-sections shown in Figure 3.12, 12% of patients had a serum ferritin ≤200 ng/mL, with 23%, 24%, 24%, and 17% of patients having serum ferritin levels of 201-500, 501-800, 801-1200, and >1200 ng/mL. Over this three-year time period, the percentage of patients with a serum ferritin >1200 ng/mL gradually increased from 16% to 19%, accompanied with small declines in the percentage of patients with serum ferritin levels of 501-800 and 801-1200 ng/mL suggesting a gradual shift over time from lower to higher serum ferritin levels. Consistent with this, the mean serum ferritin level

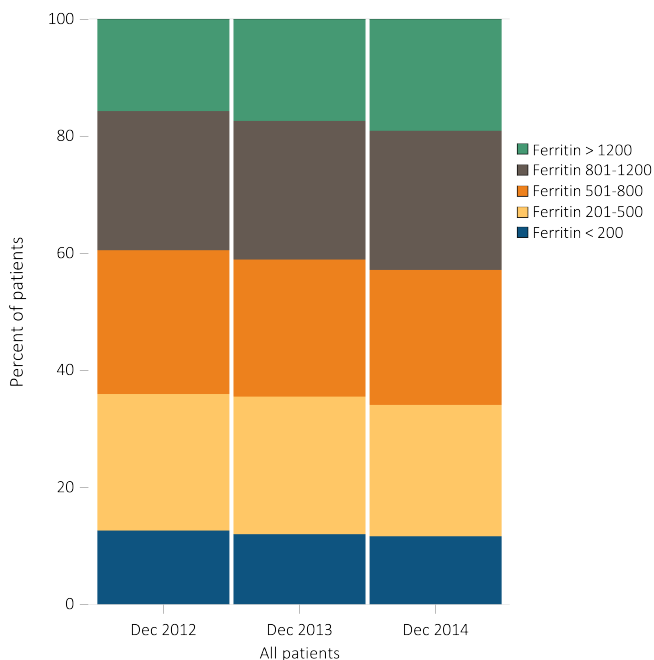
increased from 737 to 785 ng/mL from the December 2012 to December 2014 cross-section.

vol 2 Figure 3.11 Distribution of TSAT levels (%) in adult peritoneal dialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2012, 2013, and 2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2012, 2013 and 2014. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of TSAT level for that year, ≥18 years old as of December 1st of that year, and who were alive through December 31 of that year. Abbreviation: 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 1 year, CROWNWeb data, December 2012, 2013, and 2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2012, 2013 and 2014. Dialysis patients on treatment for ESRD at least 1 year 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.

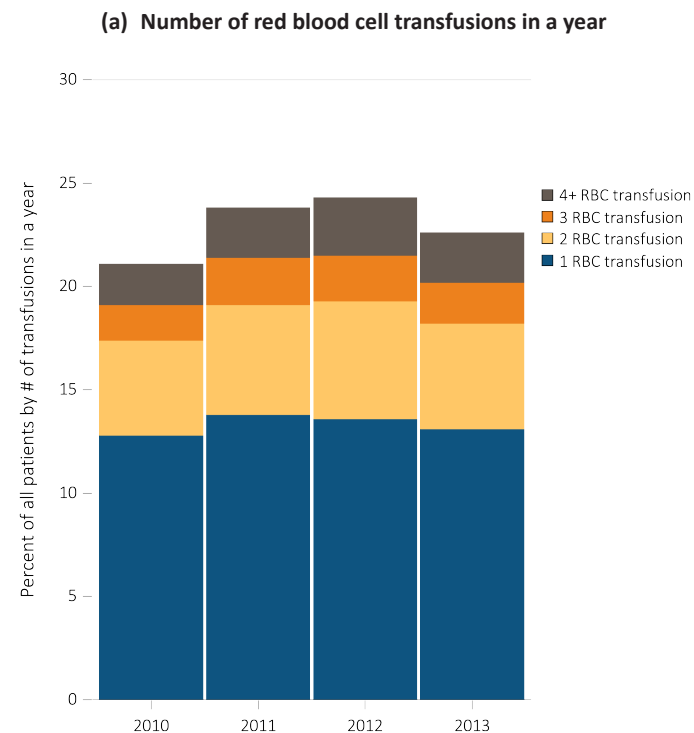
RED BLOOD CELL TRANSFUSIONS IN PERITONEAL DIALYSIS PATIENTS

The distribution of the number of red blood cell transfusions received by peritoneal dialysis patients, by year, is shown in Figure 3.13.a, for years 2010 through 2013. 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 hemodialysis therapy for the entire year, these results should be interpreted cautiously. The results indicate that 21.2% of peritoneal dialysis patients received ≥1 red blood cell transfusion in year 2010, which increased to approximately 24% of patients in years 2011 and 2012, and declined to 22.6% of peritoneal dialysis patients in 2013. Across this four-year time period, typically 13-14% of peritoneal dialysis patients received one red blood cell transfusion per year, 4.6-5.7% received two red blood cell transfusions per year, with approximately 2% receiving 3 transfusions per year, and 2-3% receiving ≥4 red blood cell transfusions per year.

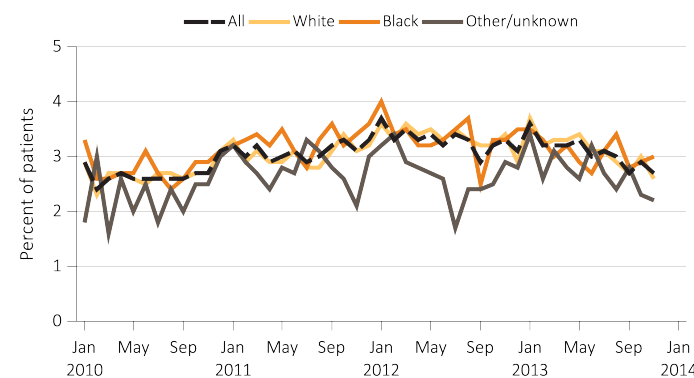
In 2013, an average of 3.1% of peritoneal dialysis patients in a month received red blood cell

transfusions both among Black and White peritoneal dialysis patients compared with 2.7% among patients of Other/Unknown race.

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 by race, from Medicare claims data, 2010-2013



(b) With ≥1 claims for a red blood cell transfusion in a month by race



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

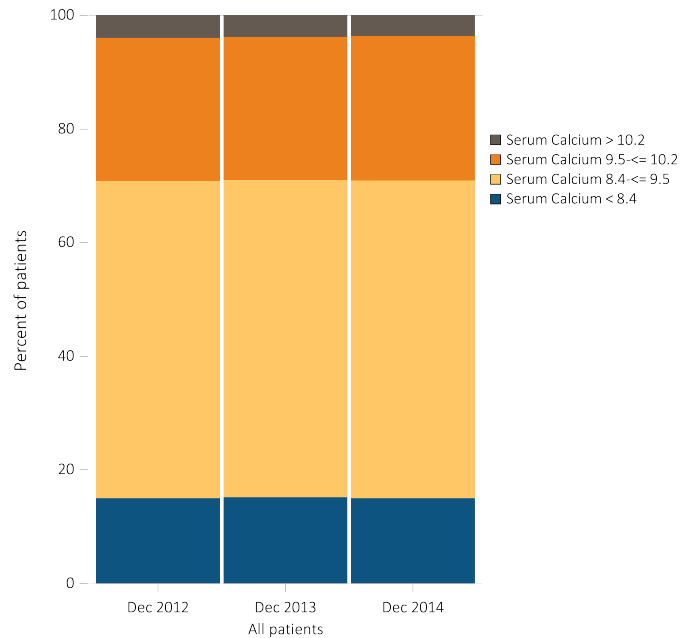
Evidence from basic scientific and epidemiological studies supports the role of abnormalities in markers of mineral and bone metabolism in the pathogenesis of vascular calcifications and cardiovascular disease,

which contributes to 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, likely mediated in part by poor nutritional status. Finally, the possibility of inappropriate treatment should be considered when a patient on chronic dialysis presents with very low levels of calcium and phosphorus. 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

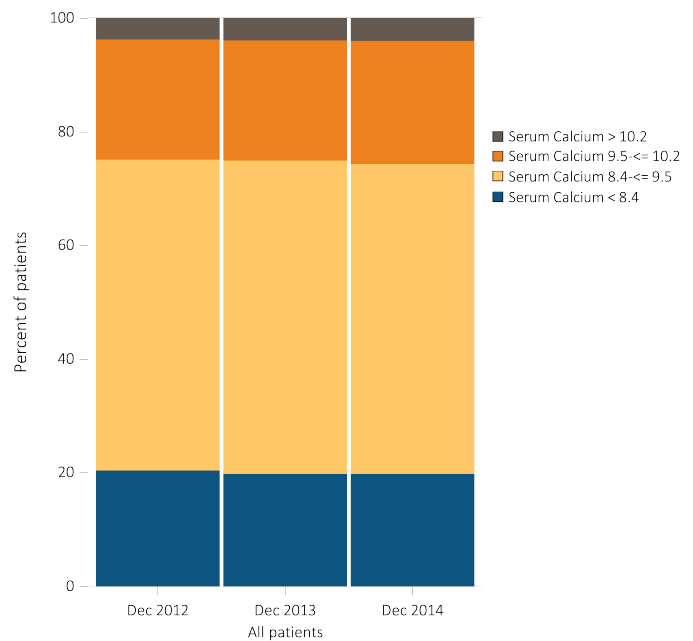
The distributions of calcium levels among adult hemodialysis and peritoneal dialysis patients are shown in Figures 3.14 and 3.15. Between 2012 and 2014, no substantial change in calcium distribution was observed. The majority of patients (hemodialysis: 56%, peritoneal dialysis: 55%) had calcium levels within a typical laboratory reference range (8.4-9.5 mg/dL), while a very small percentage (hemodialysis: 3.6%, peritoneal dialysis: 3.9%) had calcium levels >10.2 mg/dL. The 10.2 mg/dL cut point is particularly important since it approximates the one 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 (19.9 vs 15.1% in December 2014), 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 2012, 2013, and 2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2012, 2013 and 2014. 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.

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 2012, 2013, and 2014

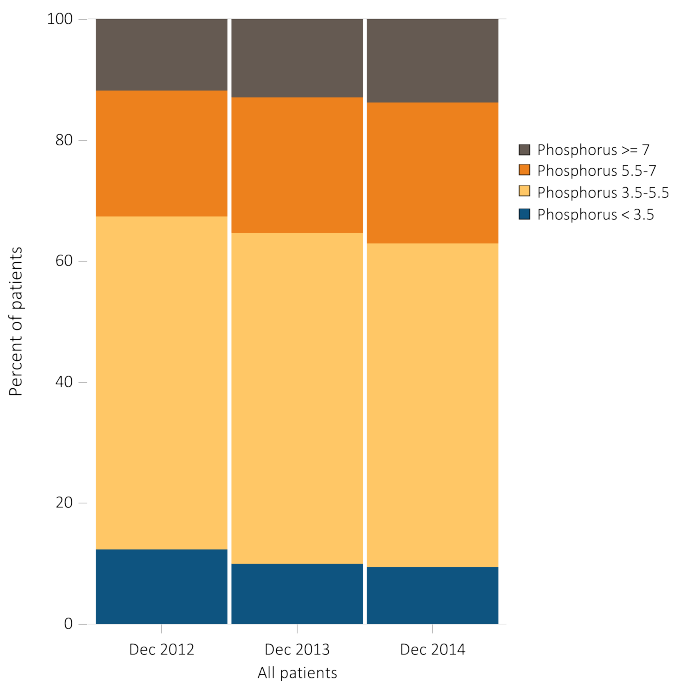


Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for October to December for years 2012, 2013 and 2014. Dialysis patients on treatment for ESRD at least 1 year at the time of measurement of serum calcium for that year, ≥18 years old as of December 1 of that year and who were alive through December 31 of that year.

PHOSPHORUS

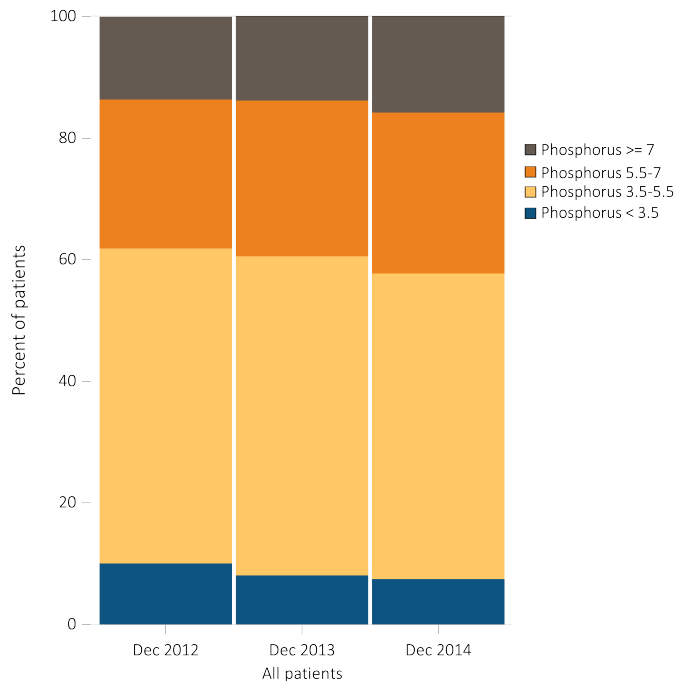
The distribution of serum phosphorus levels among adult hemodialysis and peritoneal dialysis patients are shown in Figures 3.16 and 3.17. Between 2012 and 2014, a slight increase in mean serum phosphorus was observed both in hemodialysis and peritoneal dialysis patients (hemodialysis: from 5.0 to 5.2 mg/dL; peritoneal dialysis: from 5.2 to 5.4 mg/dL). Among hemodialysis patients in December 2014, more than one-third (37%) had serum phosphorus >5.5 mg/dL, which has consistently been associated with adverse clinical outcomes. This percentage was even higher among patients on peritoneal dialysis (42%). It should be noted that 5.5 mg/dL is higher than the current KDIGO guidelines recommendation, which is to maintain phosphorus levels within the laboratory reference range (typically between 2.5 and 4.5 mg/dL). When using this more stringent criterion, 68% of hemodialysis and 71% of peritoneal dialysis patients had elevated phosphorus levels, indicating a clear opportunity for improvement. The prevalence of low phosphorus levels (<3.5 mg/dL) declined slightly over time, to 10% in hemodialysis patients and 8% in peritoneal dialysis patients in December 2014.

vol 2 Figure 3.16 Distribution of serum phosphorus (%) levels in adult hemodialysis patients on dialysis for at least 1 year, CROWNWeb data, December 2012, 2013, and 2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2012, December 2013, and December 2014. 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.

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 2012, 2013, and 2014



Data Source: Special analyses, USRDS ESRD Database. CROWNWeb clinical extracts for December 2012, December 2013, and December 2014. 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.

Preventive Care

DIABETES MELLITUS

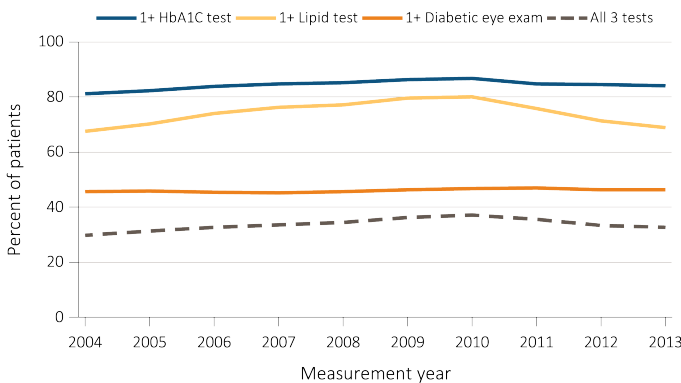
Recommendations for glycemic and lipid monitoring, treatment, and target levels in diabetic patients with ESRD are controversial. The role of regular dilated eye exams and timely treatment in preventing vision loss is, however, well-established.

From 2003 to 2010, there was a steady increase in the percentage of ESRD patients with diabetes receiving at least one HbA1c test and at least one lipid test per year (86% with at least one HbA1c test and 80% 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 HbA1c test and 85% with at least one lipid test in 2009) and in the Medicare population with diabetes (90% with at least one HbA1c 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). Over the past three years, there has been a slight decrease in the percentage of patients with diabetes receiving at least one HbA1c test per year and a more substantial decrease

in the percentage of patients receiving at least one lipid test per year (Figure 3.18). The decrease in HbA1c testing may reflect an increasing awareness of the limitations of HbA1c 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 HbA1c or 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%), whereas the performance of all three tests (approximately 33% in the most recent year) has fallen slowly over the last three years, in line with the declines in HbA1c and lipid testing. 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, 2004-2013



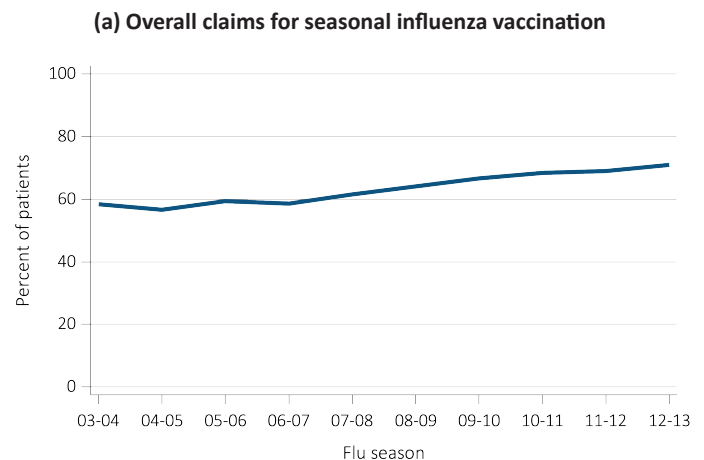
Data Source: Special analyses, USRDS ESRD Database. Point prevalent Medicare ESRD patients aged 18 to 75 years with a diagnosis claim for diabetes mellitus in the previous year; diabetes-related care in the measurement year. Abbreviations: ESRD, end-stage renal disease; HbA1C, glycosylated hemoglobin.

VACCINATION

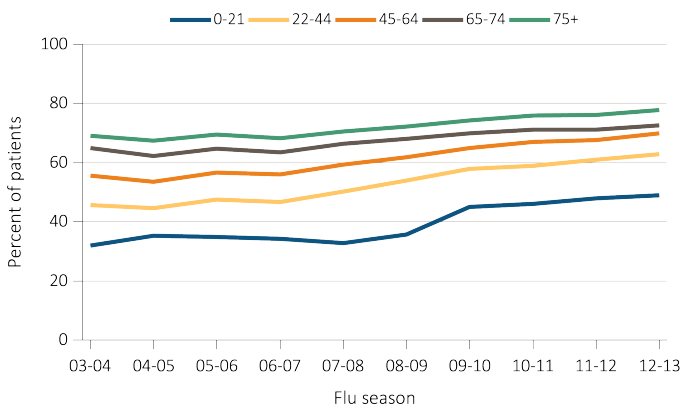
Yearly influenza vaccination is recommended for all ESRD patients. Seasonal influenza vaccination is defined here more broadly than the typical October

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% in the 2003-2004 season to 71% in the 2012-2013 season (Figure 3.19.a); however, this is still below the Healthy People 2020 (HP2020) target of 90%. The percentage of patients vaccinated is highest in older age groups, with only 49% of ESRD patients aged 0-21 years vaccinated in the 2012-2013 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% in the 2012-2013 season (Figure 3.19.c). By modality, hemodialysis patients were vaccinated at the highest frequency (75% in the most current data), compared with 72% in peritoneal dialysis patients, and 56% 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 theoretical concern 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.

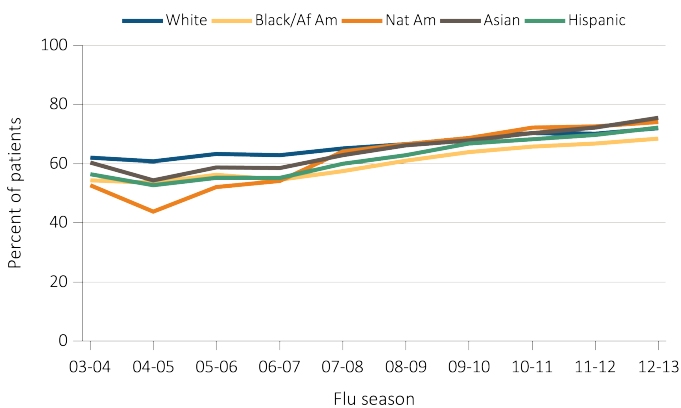
vol 2 Figure 3.19 Percentage of ESRD patients with a claim for seasonal influenza vaccination (August 1-April 30 of subsequent year), (a) overall, (b) by age, (c) by race/ethnicity, (d) by modality Medicare data, 2003-2013



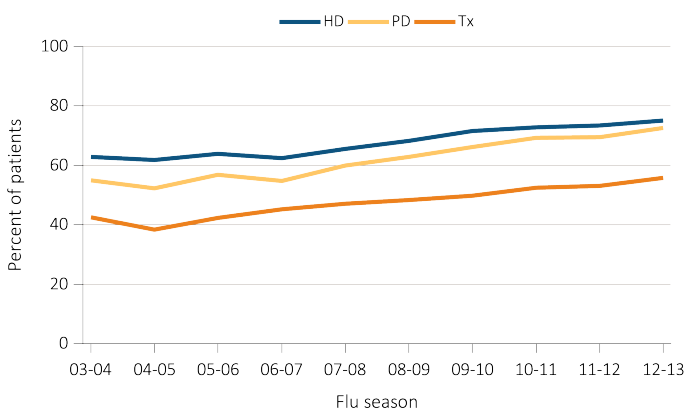
(b) Age



(c) Race/Ethnicity



(d) Modality



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

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.

References

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Notes