Chapter 2: Clinical Indicators and Preventive Care

Anemia

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

Serum Albumin

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

Mineral and Bone Disorders

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

Preventive Care

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

Introduction

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

Methods

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

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

Clinical Indicators

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

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

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

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

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