Hemoglobin is an iron-rich protein that attaches to oxygen in the lungs and carries it to tissues throughout the body. Anemia is said to occur when hemoglobin levels are less than 13.0 gm/dL in males or less than 12.0 gm/dL in females. However, it has been recommended that healthcare providers consider the use of erythropoiesis-stimulating agents (ESAs) for hemoglobin production only when a patient’s hemoglobin level is below 10 g/dL.

Anemia commonly occurs in people with chronic kidney disease (CKD), a condition in which patients experience a progressive loss of kidney function over time. Anemia might begin to develop in the early stages of CKD, when someone has 20 to 50 percent of normal kidney function, and tends to worsen as CKD progresses. About 30 million people in the United States (15% of adults) are estimated to have CKD.

ESAs are commonly used to treat anemia in patients with CKD, including those receiving dialysis. In 2011, the Food and Drug Administration (FDA) introduced recommendations for more conservative dosing of ESAs in patients with CKD. FDA made these recommendations based on data showing increased risk of cardiovascular events, including stroke, heart attack, heart failure, blood clots, and death, in patients using ESAs.

The Medicare Improvement for Patients and Providers Act (MIPPA), implemented in 2011 by the Centers for Medicare & Medicaid Services (CMS), covers patients whose CKD has progressed to end stage renal disease (ESRD) and requires hemodialysis. MIPPA directed that hemodialysis services provided to ESRD patients be reimbursed using a bundled, comprehensive payment system. This system does not provide separate payments for individual covered services such as hemodialysis itself, ESAs and other medications, and laboratory testing associated with each hemodialysis treatment. Reimbursement for blood transfusions (e.g., for more severe anemia) is separate and not included in the bundled payments.

Thus, after many years of escalation, ESA use patterns changed markedly in response to negative safety reports, product labeling changes, black box advisories, revised anemia management guidelines, and reimbursement changes. Associated National Healthcare Quality and Disparities Report data on anemia frequency in hemodialysis patients show significant increases after 2011 (Figure 1).
Figure 1. Hemodialysis patients whose hemoglobin level is less than 10 g/dL, by race, 2006-2015

Key: AI/AN = American Indian/Alaska Native.

◆ From 2006 to 2015, the percentage of hemodialysis patients whose hemoglobin level was less than 10 g/dL increased from 1.7% to 16.8%.
◆ The percentage of hemodialysis patients with hemoglobin below 10 g/dL increased from 1.5% to 15.6% for Whites, from 2.1% to 19.0% for Blacks, from 1.1% to 13.8% for Asians, and from 1.3% to 13.7% for Alaskan Indians/Alaska Natives (AI/ANs).
In 2015, Asian and AI/AN hemodialysis patients were less likely than Whites to have a hemoglobin level less than 10 g/dL but Black hemodialysis patients were more likely than Whites to have a hemoglobin level less than 10 g/dL (Figure 2).

Several programs are working to reduce the prevalence of anemia and improve quality of life for ESRD patients receiving dialysis, including:

- The ESRD Quality Improvement Program (QIP) is a pay-for-performance program CMS started in 2012 to improve the quality of care provided to ESRD patients. QIP provides a financial incentive for renal facilities to deliver high-quality patient care, including anemia management.

- The National Kidney Foundation produces clinical practice guidelines through the Kidney Disease Outcomes Quality Initiative (KDOQI). This program has provided evidence-based guidelines (most recently updated in 2015) and is recognized throughout the world for improving the diagnosis and treatment of kidney disease. In addition to guideline development, KDOQI aims to improve clinical practice through collaboration with wider policy and education programs designed to support implementation of guideline recommendations.
References


