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Take Posttest

Action Points

WASHINGTON -- Hemoglobin levels in dialysis patients have fallen in concert with Medicare's bundling system of reimbursement and label changes on erythropoiesis stimulating agents (ESAs), researchers said here.

Data from two monitoring systems revealed about a 0.4 g/dL drop in hemoglobin levels in 2011 over previous stable years, with corresponding declines in ESA doses and an uptick in blood transfusions that had some clinicians at the National Kidney Foundation meeting concerned.

"What's bad about blood transfusion is that it reduces access to subsequent kidney transplantation" because of increased problems with organ matching, said Joseph Vassalotti, MD, chief medical officer of the NKF. He noted, however, that it's too early for data to show whether kidney transplants -- or other patient care outcomes such as quality of life -- have been affected.

The changes in hemoglobin levels have been prompted by two events. First, Medicare

implemented the 'bundle' system of reimbursement for dialysis treatment in January 2011, which pays a flat rate of $230 per dialysis treatment, including lab work and intravenous medications such as ESAs, vitamin D, and iron. (The cost of oral medications will be added into the bundle in January 2014.)

In June of 2011, the FDA changed labeling on ESAs that specified a target hemoglobin range of 10 to 12 g/dL for dialysis patients. Instead, the agency said, ESA therapy should be started only if levels fall below 10 g/dL and the dose should be reduced or interrupted once levels hit 11 g/dL.

The agency had cited concerns about an increased risk of cardiovascular events as the reason for the label change, but clinicians have noted that the bundling measures were intended to curb the overuse of the costly ESAs -- the second most expensive component of dialysis, aside from the procedure itself.

Analyses from two databases -- the U.S. Renal Data System (USRDS) and the Dialysis Outcomes and Practice Patterns Study (DOPPS) -- reported similar findings at two separate sessions here.

Allan Collins, MD, of the University of Minnesota and director of the USRDS coordinating center, found that mean hemoglobin levels fell 3.8% between 2009 and the first nine months of 2011, from 11.39 g/dL to 10.96 g/dL.

The drop corresponded with a 19.2% drop in ESA doses and a 3.4% increase in use of IV iron during that time.

Though the data didn't show an increase in hospitalizations, researchers were concerned by the rise in blood transfusions, which had remained largely stable in 2009 and 2010. In September 2011, however, there were 0.036 transfusions per patient per month, compared with about 0.030 in that month for both prior years -- a trend that accelerated after the ESA label changes.

The result could be a reduced likelihood of eligibility for kidney transplant, but there aren't yet

data to determine whether this has been the case: "How much it will decrease access is a complicated question," said Vassalotti, who chaired the session during which the USRDS data were presented.

He added that the transfusion rates seen in the study may be underreported because the dialysis centers included in the surveillance system may not necessarily keep accurate tabs on the number of patients hospitalized outside of their centers for transfusion.

Data from DOPPS, an international 12,000-patient dataset that tracks 140 U.S. dialysis facilities and about 5,000 U.S. patients, revealed similar trends, although it did notice an uptick in hospitalizations.

Median hemoglobin levels fell 0.08 g/dL between August 2010 and July 2011, and by an additional 0.37 g/dL through October 2011, which reflects a sharper decline after the ESA label change, Bruce Robinson, MD, of Arbor Research in Ann Arbor, Mich., told *MedPage Today*.

Weekly ESA doses fell a median of 23% between August 2010 and December 2011, again with the sharpest decline after the label changes, Robinson said.

Levels of IV iron use steeply increased from 57% of patients getting iron in 2010 to 77% receiving it in December 2011. That corresponded with rises in serum ferritin -- a median 25% increase over that time -- although the potential long-term consequences of this finding aren't clear, Robinson said.

DOPPS also captured a jump in parathyroid hormone levels, which rose a median of 31% between August 2010 and April 2011, stabilizing through December 2011. There were no clear changes, however, in serum calcium or phosphate and no clear trends in the use of IV vitamin D, phosphorus binders, or cinacalcet, he reported.

As with the USRDS, Robinson and colleagues also saw a rise in transfusions, jumping from 2.21% of patients transfused in the hospital per month in September 2010 to 4.87% in September 2011, adding again that the database has capture issues with transfusion data

because not all dialysis centers are aware of hospital-based transfusions.

And DOPPS data did show a rise in hospitalization rates, from 1.5% in August 2010 to just over 1.8% in November 2011 -- a trend that warrants closer monitoring, Robinson said.

The database also tracks international trends, and Robinson said hemoglobin levels in the U.S. appear to have fallen more in line with those of Europe and Japan since the policy changes.

He added that the Centers for Medicare and Medicaid Services recently convened a panel of technical experts to deal with these new challenges in anemia management, including the possibility of implementing pay-for-performance measures tied to limiting the number of transfusions -- which may "point to a need for improved coordination of care and accountability across healthcare settings."

Vassalotti noted, however, that the big question remains: have the changes affected patient quality of life?

"It's hard to measure that," he told *MedPage Today.* "We don't have good data yet."

Collins reported relationships with Johnson & Johnson, Merck, Takeda, Affymax, NxStage, Amgen, Abbott, Medtronic, GlaxoSmithKline, and Reata.

The DOPPS database is supported by a consortium of industry sponsors, including Amgen, Kyowa Hakko Kirin, Genzyme, and Abbott.

Vassalotti reported relationships with CTI Clinical Trials, Gore Creative Technologies and Elsevier Health.

Primary source: National Kidney Foundation meeting
Source reference:
Collins AJ "ESRD payment policy changes: The new 'bundled' dialysis prospective payment system in the US" *NKF* 2012.

Additional source: National Kidney Foundation meeting
Source reference:
Robinson BM, et al "The impact of bundling on clinical practice: Changes in practice patterns & laboratory values" *NKF* 2012.

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