



Unintended Consequence for Dialysis Patients as Drug Rule Changes



Noah Berger for The New York Times

A patient waiting for a kidney got dialysis. More dialysis patients are getting blood transfusions.

By KEVIN SACK
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A shift last year by the federal government in how it pays for drugs to treat dialysis patients may have had an unintended and potentially dire consequence, according to new research: a significant jump in blood transfusions for patients who now may not be getting enough of the medications.

The findings are seen by some experts as a stark illustration of how the government's reimbursement policies can drive the practice of medicine.

The policy shift was intended to save money and protect patient health by correcting what federal regulators saw as a misguided financial incentive for dialysis centers to overprescribe anti-anemia drugs.

Previously, the government had paid dialysis centers for these drugs separately from the actual blood-cleansing treatments, effectively encouraging their overuse. That created health hazards, as well, because the high red blood counts produced by overuse of the drugs carry a heightened risk of heart attack and stroke.

So the federal Medicare program, which covers the treatment of life-threatening renal conditions, regardless of a patient's age, changed its payment system to reimburse for overall care, bundling together the cost of treatment and drugs. For the dialysis centers, that instantly transformed the expensive drugs from a profit center to a drain on profits.

The new research, to be presented Friday to a meeting of the National Kidney Foundation in Washington, found that dialysis clinics were prescribing less of the drugs, as the government intended. But the transfusion numbers suggest that dialysis providers, driven by the revised incentives and new usage guidelines, have yet to find the right medication level for some patients.

According to the United States Renal Data System, in each of the first nine months of 2011, the share of dialysis patients covered by Medicare who received blood transfusions increased by 9 to 22 percent over the corresponding months in 2010. Last September, for instance, there were 10,041 transfusions for dialysis patients, compared with 8,259 for the

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same month in 2010. There had been virtually no change in transfusion rates between 2009 and 2010.

The implications can be foreboding for patients awaiting kidney transplants because transfusions, along with pregnancies and prior transplants, can change body chemistry and make it more difficult to find a compatible organ. That makes them more likely to be among the 4,500 Americans who die each year while waiting for kidney transplants.

"It's a clinically significant finding," said Dr. Allan J. Collins, the data group's director. "And we didn't anticipate an increase of this magnitude. While it's important that the overprescription of these drugs is being disincentivized, we're seeing evidence that their underuse with low hemoglobins may also have real consequences for potential transplant candidates. These transfusions can significantly lower their chances at finding a match." Although the new study was financed by the National Institutes of Health, Dr. Collins also conducts research with backing from major renal drug companies.

Dr. Collins and officials with the Centers for Medicare and Medicaid Services said it was too early to know whether the payment changes had slowed the growth of spending. Medicare spends [more than \\$30 billion a year](#) on the treatment of [end-stage kidney disease](#), including about \$2 billion for anti-anemia drugs, which are known as erythropoiesis-stimulating agents.

There are 400,000 Americans on dialysis. Without the drugs, many face debilitating anemia, because kidney disease limits the production of a hormone that stimulates the generation of red blood cells.

"You just feel like a washrag," said Lori Hartwell, a recent transplant recipient, and the founder of a patient advocacy group called the [Renal Support Network](#). "It's hard to get out of a chair. You just don't have any energy."

Six years ago, as concern mounted in Washington about the escalating cost of the anti-anemia medications, researchers began to find evidence of an increased risk of cardiovascular problems in kidney patients whose blood counts had been driven to high levels by the drugs. The leading product in the field is Epogen, made by Amgen.

Under orders from Congress, the Medicare agency issued new rules, effective in January 2011, to start paying dialysis clinics a flat rate of about \$230 per treatment that would include the cost of medications.

In June of the same year, the Food and Drug Administration changed its labeling for the drugs as a caution against overuse. It lowered the high end of the range of [hemoglobin](#) levels recommended for patients using the drugs. And it advised doctors to use the lowest doses possible to avoid transfusions, a level that might vary by patient.

The next month, the Medicare agency added financial teeth by proposing that it would dock reimbursements to dialysis centers when patients had hemoglobin counts above a certain level, but not when they fell beneath any particular point.

Although the new study found that transfusions rose as soon as the bundled reimbursement rate took effect in January, it also detected a spike to even higher levels after the punitive Medicare policy was proposed. The researchers calculated that the average dosage of anti-anemia drugs taken by dialysis patients decreased by 18 percent from 2010 to 2011.

Officials with the F.D.A. and Medicare said the findings would be reviewed to determine whether drug usage guidance or reimbursement policy should be revised.

"It's going to take careful study to understand what the trade-off is, what the balance is," said Dr. Robert Kane, deputy director for safety in the F.D.A.'s division of hematology products. "The F.D.A. has never taken the position that the drugs lack a benefit. There is a benefit. The question is what's the right amount."

Dr. Patrick H. Conway, chief medical officer of the Centers for Medicare and Medicaid Services, said his agency would closely monitor the impact of payment changes on renal patients, "including any potential unintended clinical changes in beneficiary care such as increases in blood transfusions."

Several renal experts said it might be seen as an acceptable trade-off to exchange a higher risk of cardiovascular attack for a higher risk of transfusion. "They've traded one problem for another," said Dr. Jay B. Wish, medical director of the dialysis program at Case Western Reserve University's medical center in Cleveland. "And the question is are the patients worse off, and that remains to be seen."



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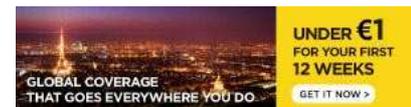
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