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Dialysis Facility Profit Status and Compliance With a Black Box Warning

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Erythropoiesis-stimulating agents (ESAs) for treatment of anemia in dialysis patients are a substantial Medicare drug expenditure.¹ In 2011, the Centers for Medicare & Medicaid Services implemented a “bundled” reimbursement system that provides a single payment for all dialysis services, including ESA administration.² A major objective of the bundled system was to contain the cost of medications administered during dialysis, which were previously separately billed.³

The new reimbursement system will fundamentally reverse the incentives in dialysis from providing more to less care and creates the possibility of underutilization not only of ESAs but also of other services that are beneficial for patients receiving dialysis, such as administration of antibiotics during dialysis. However, these issues are important only if there is reason to believe that dialysis facilities might consider financial goals in clinical decision making.

Dialysis facilities previously faced a tension between clinical and cost considerations when the US Food and Drug Administration (FDA) issued a black box warning in 2007 calling for use of the lowest possible ESA dose to avoid the need for blood transfusion and for

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Author Contributions: Drs Ishida and Grimes had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Ishida, McCulloch, Dudley, and Johansen. *Acquisition of data:* Johansen. *Analysis and interpretation of data:* All authors. *Drafting of the manuscript:* Ishida. *Critical revision of the manuscript for important intellectual content:* All authors. *Statistical analysis:* Ishida, McCulloch, and Grimes. *Obtained funding:* Johansen. *Administrative, technical, and material support:* Johansen. *Study supervision:* McCulloch, Dudley, and Johansen.

Conflict of Interest Disclosures: Dr Grimes has received research funding from Dialysis Clinic, Inc. Dr Johansen serves on the Amgen National Nephrology Advisory Board.

Disclaimer: The data reported herein have been supplied by the US Renal Data System. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy or interpretation of the US government.

Previous Presentation: This study was presented in part as a poster at Kidney Week 2012 (annual meeting of the American Society of Nephrology); November 2, 2012; San Diego, California.

Online-Only Material: The eMethods, eTable, eFigure, and eReferences are available at <http://www.jamainternalmed.com>.

withholding ESA if a patient's blood hemoglobin level exceeded 12 g/dL (to convert to grams per liter, multiply by 10).⁴ For-profit dialysis providers historically have used higher ESA doses than nonprofit providers, perhaps in response to financial incentives to maximize profit.⁵ It is unknown whether the safety directive and explicit clinical instructions provided by the black box warning reduced or eliminated this behavior. To assess the extent to which the response to the black box warning for ESAs differed according to profit status, we studied ESA dosing and hematocrit levels among for-profit and nonprofit dialysis providers before and after the black box warning was issued.

Methods

From the US Renal Data System, we identified 275 291 Medicare-covered adults receiving in-center hemodialysis as of February 1, 2007 (before the warning); February 1, 2008 (after the warning); or both time points. We calculated weekly ESA (epoetin alfa and darbepoetin alfa) dose and mean hematocrit level for each patient in February 2007 and/or February 2008. We evaluated the association between year, profit status, and weekly ESA dose overall and stratified by hematocrit category while adjusting for case mix and accounting for correlation of data within dialysis chains, facilities, and (if needed) patients using mixed models incorporating these factors as random effects. We also analyzed within-patient change in ESA dose among those who received hemodialysis during both time points accounting for clustering by chain, facility, and patient. (See eMethods for further detail; <http://www.jamainternalmed.com>.)

Results

The median (interquartile range) age of the overall cohort was 64 (52-74) years; 54% were men and 55% were white. (See eTable for demographic characteristics by year and profit status.) For-profit facilities used higher median weekly ESA doses overall (9020 [95% CI, 8604-9455] vs 5670 [95% CI, 5381-5974] units in February 2007 and 8322 [95% CI, 7937-8725] vs 5063 [95% CI, 4801-5337] units in February 2008) and in every hematocrit category (**Figure**) than nonprofit facilities after adjustment for case mix ($P<.001$ for all comparisons). Among patients who switched from a nonprofit to a for-profit facility between the prewarning and post-warning time points, median weekly ESA dose increased 54.7%, and among patients who switched from a for-profit to a nonprofit facility, median weekly ESA dose decreased 50.9% (eFigure). The increase in the proportion of patients with hematocrit level less than 30% after the warning was relatively small and of equal magnitude in for-profit (from 6.5% to 8.8%) and nonprofit (from 6.5% to 8.8%) facilities. The percentage of patients with hematocrit level of at least 39% was substantially reduced after the warning in for-profit (from 17.2% to 8.8%) and nonprofit (from 18.0% to 8.7%) facilities.

Discussion

Our results show that, despite the FDA's safety directive to use the minimum necessary ESA dose, for-profit facilities continued to prescribe more ESAs than nonprofit facilities after the

black box warning at every hematocrit level and performed no better than nonprofit facilities in avoiding a hematocrit level of less than 30%.

Given the observational nature of this study, we cannot assert a causal relationship between profit status and ESA dosing. However, during the time period examined in our study, the bundled payment system had not yet been implemented, and the incentive was still in place to maximize profit by administering more ESA. The observation of higher ESA dosing in for-profit facilities, particularly among patients who switched from a nonprofit to a for-profit facility and patients with a hematocrit level above the recommended range, suggests that financial considerations may have played a role in ESA dosing in for-profit facilities. Limitations of our study include ascertainment of clinical data from an administrative database and the possibility of incomplete control for confounding.

As dialysis care has become predominantly consolidated into for-profit large dialysis organizations,⁶ the implications of the differential ESA use for patient outcomes and safety warrant continued evaluation. Although the new bundled reimbursement system was implemented in part as a cost-controlling measure, it changes the financial incentives regarding ESA and also creates incentives regarding many other aspects of dialysis care. Our data suggest that it will be important, with these new incentives, to monitor changes in dialysis care and outcomes.

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References

1. US Renal Data System. USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the US. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; Bethesda, MD: 2012.
2. Collins, AJ. [July 24, 2012] ESRD Payment Policy Changes: The New “Bundled” Dialysis Prospective Payment System (PPS) in the United States. US Renal Data System website. 2012. http://www.usrds.org/2012/pres/USDialysisBundle_impact_NKFCM2012.pdf.
3. Centers for Medicare & Medicaid Services. Medicare programs; end-stage renal disease prospective payment system. Fed Regist. 2009; 74(187):49924. 42 CFR §§410, 413, and 414.
4. US Food and Drug Administration. [May 24, 2012] Information for Healthcare Professionals: Erythropoiesis Stimulating Agents (ESA) [Aranesp (darbepoetin), Epogen (epoetin alfa), and Procrit (epoetin alfa)]. 2007. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126485.htm>.
5. Thamer M, Zhang Y, Kaufman J, Cotter D, Dong F, Hernán MA. Dialysis facility ownership and epoetin dosing in patients receiving hemodialysis. JAMA. 2007; 297(15):1667–1674. [PubMed: 17440144]
6. US Renal Data System. USRDS 2011 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the US. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; Bethesda, MD: 2011.

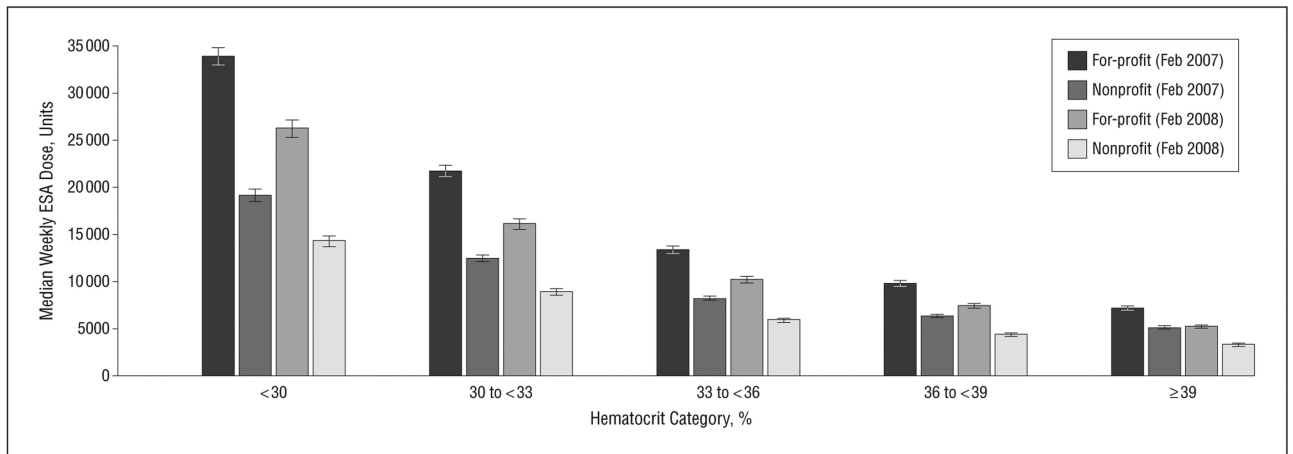


Figure. Median weekly erythropoiesis-stimulating agent (ESA) dose by year, profit status, and hematocrit category. Error bars indicate \pm standard error (derived on the log-transformed scale).