Lost Without Directions: Lessons from the Anemia Debate and the Drive Study

David M. Spiegel* and Glenn M. Chertow†

*University of Colorado Denver Health Sciences Center, Division of Renal Diseases and Hypertension, Aurora, Colorado; and †Stanford University School of Medicine, Division of Nephrology, Stanford, California

Growing concerns related to the potential hazards of erythropoiesis stimulating agents have led to downward adjustment in hemoglobin targets for patients with chronic kidney disease, including patients with ESRD on dialysis. These concerns, coupled with economic pressures and shifting cost structures in dialysis funding, have prompted new strategies directed toward the optimal management of anemia, including the call for more liberal use of intravenous iron (1). This article highlights the limited evidence base in support of alternative anemia management strategies and cautions against the injudicious use of iron in this patient population in the absence of sufficient data on long-term safety.


Published online ahead of print. Publication date available at www.cjasn.org.

Correspondence: Dr. David M. Spiegel, University of Colorado Denver Health Sciences Center, Division of Renal Diseases and Hypertension, 12700 East 19th Avenue, C281, Aurora, CO 80045. Phone: 303-399-6997; Fax: 303-399-3131; E-mail: david.spiegel@ucdenver.edu

Copyright © 2009 by the American Society of Nephrology

ISSN: 1555-9041/405–1009
quate to justify the administration of IV iron to patients with underlying inflammatory processes, as seen in the DRIVE trials in which the average high-sensitivity C-reactive protein was 27.0 ± 33.7 mg/L. Although we have focused on the potential harm of overutilization of ESAs, we should be mindful that the long-term safety of unbridled IV iron administration has never been established. There is no evidence to support the assumption that achieving a target hemoglobin concentration in patients on dialysis with evidence of ongoing inflammation by using less ESA and more IV iron will prove safer than trying to achieve that target with more ESA or any other potential strategy. For better or worse, with the scepter of bundling looming on dialysis providers, assuming that target hemoglobin concentrations are still considered valid clinical performance measures, we will likely observe increased iron utilization to minimize ESA usage in the interests of reducing costs as suggested in a recent cost-savings analysis of the DRIVE study (6). What we have truly learned from the anemia debate and the DRIVE studies is that given the right environment, economic policy, pharmaceutical marketing, and open market forces may drive patient care without adequate attention to patient safety. As a scientific community we need to pay close attention to the limitations of the current data and begin to step up to our responsibilities by demanding adequately powered, well designed, randomized clinical trials with clinically relevant endpoints and the adequate collection of safety information. Perhaps it is time for CMS and/or the large dialysis organizations to sponsor these trials, ensuring that they are implemented and interpreted by experts drawn from diverse groups within and outside of the nephrology community.

Disclosures
Both authors have received grant funding from Amgen, Inc. Dr. Spiegel has served on Amgen advisory boards.

References