

IV Iron Therapy and Anemia Management In Patients on Hemodialysis: Benefits Of a Revised CQI Strategy

Deborah Bowe

Anemia is a common problem in patients with chronic kidney disease (CKD) or end stage renal disease (ESRD) receiving hemodialysis. Anemia (defined as hemoglobin [Hgb] less than 12.0 g/dL in men and less than 11.0 g/dL in women) occurs in about 44% of patients with stage 4 CKD and nearly all patients with stage 5 CKD (Nurko, 2006). Anemia is associated with a broad range of adverse consequences in patients on hemodialysis, including cognitive dysfunction, increased risk of hospitalization, poor cardiovascular outcomes, increased health care costs, and decreased quality of life (Dowling, 2007).

Treatment with erythropoiesis-stimulating agents (ESAs) is the hallmark of anemia management in patients on hemodialysis. ESA treatment is effective in the majority of these patients with anemia, but pharmacologically induced erythropoiesis is limited by the available iron supply. Iron deficiency develops in most patients receiving ESA therapy while on hemodialysis because of the increased demand for iron due to ESA-driven accelerated erythropoiesis combined with ongoing blood

Intravenous iron therapy is widely used in the management of anemia in patients on hemodialysis, and anemia management protocols provide a standardized approach to IV iron therapy. The author's hemodialysis center implemented an initial anemia management protocol in 2004 based on the principles of a continuous quality improvement (CQI) program, detailed by Bowe and Ammel in the Nephrology Nursing Journal in 2005. Successive revision using the CQI process has resulted in additional benefits regarding patient outcomes, which are reported here. This article illustrates the value of a CQI program for maintaining and improving clinical outcomes in patients who have anemia and are undergoing hemodialysis.

Goal

To illustrate how the successive use of a continuous quality improvement program for maintaining and improving an intravenous iron and anemia management protocol can improve patient outcomes.

Objectives

1. Describe the revision of an anemia management protocol in the context of an established CQI process.
2. Explain how evidence-based literature on erythropoietin-stimulating agents and IV iron therapy should be used to drive CQI revision.
3. Evaluate the effects on patient outcomes of a revised anemia management protocol using the CQI process.

losses (Nissenson & Strobos, 1999).

Iron supplementation is an important adjunct to ESA therapy in patients on hemodialysis with anemia (Eschbach, 1999; Gallieni, 1998). Intravenous (IV) iron supplementation is the preferred route of administration for achieving recommended iron levels in this population (Baile, Johnson, & Mason, 2000). IV iron supplementation helps overcome ESA resistance, resulting in enhanced erythropoiesis as measured by decreased ESA dose requirements.

The hematologic safety and efficacy of IV iron supplementation in patients on hemodialysis with anemia are well established (Besarab et al., 2000; Chang, Chang, & Chiang, 2002; Charytan et al., 2001; Michael et al., 2002; Nissenson, Lindsay, Swan, Seligman, & Strobos, 1999).

Anemia management in patients on hemodialysis can benefit from the implementation of a protocol for IV iron supplementation. One approach is to establish a continuous quality improvement (CQI) program. One of

Deborah Bowe, RN, CNN, is a Clinical Administrator, Kidney Institute of Wisconsin, LLC, Glendale, WI, and a Member of ANNA's Wisconsin Chapter #304.

Acknowledgments: The author acknowledges the assistance of David S. MacDougall and Liz Turrin in the preparation of this manuscript. Writing assistance was provided with support from Watson.

Disclosure Statement: The author reported that she is on the Watson Pharmaceuticals Speakers' Bureau.

Note: This article is supported by a financial grant from Watson Pharma, Inc. This article has undergone peer review. The information in this article does not necessarily reflect the opinions of ANNA or the sponsor.

This offering for 1.4 contact hours is being provided by the American Nephrology Nurses' Association (ANNA).

ANNA is accredited as a provider of continuing nursing education (CNE) by the American Nurses Credentialing Center's Commission on Accreditation.

ANNA is a provider approved by the California Board of Registered Nursing, provider number CEP 00910.

This CNE article meets the Nephrology Nursing Certification Commission's (NNCC's) continuing nursing education requirements for certification and recertification.

the many advantages of such a program is the ability to constantly refine an initial protocol based on the repeated evaluation that occurs during the program. In 2004, the authors developed a successful CQI process to simplify IV iron administration and achieve optimal Hgb levels in their large hemodialysis center. That process was described in detail by Bowe and Ammel (2005) in *Nephrology Nursing Journal*. This report describes how their continued use of the CQI process enables them to evaluate and improve their anemia management protocol.

Value of CQI in Anemia Management

CQI programs provide an opportunity to enhance patient safety, increase patient satisfaction, standardize practices, decrease costs and waste, improve documentation, and increase revenue and reimbursement. CQI is a philosophy of management based on the regular monitoring of data and trends, and periodic evaluation and updating of processes to generate improved patient outcomes. Key elements of a CQI program include the organization of a management team, benchmarking of current processes, identification of opportunities for improvement, initiation of a plan of intervention, evaluation of results, and revision of the management plan as necessary.

In hemodialysis facilities, CQI programs are an important adjunct to anemia management protocols (Gil-martin, Na-Thalang, Aruda, & Lau, 2004; Trenkle, 2001), which provide a standardized process for achieving and maintaining target Hgb levels. Such programs encourage a consistent therapeutic approach by establishing evidence-based definitions of target Hgb levels, ESA dosing and iron supplementation parameters, and processes for managing inadequate therapeutic responses (Michael, 2005). CQI programs can enhance the effectiveness of anemia management programs by identifying opportunities for improvement and provid-

ing a blueprint for achieving enhanced patient outcomes. According to new ESRD regulations by the Centers for Medicare and Medicaid (CMS), CQI programs (known as quality assessment and performance improvement programs) will be required in all outpatient hemodialysis units effective October 14, 2008 (CMS, 2008).

2004 CQI Program

In the spring of 2004, the author's outpatient dialysis center, the Milwaukee Nephrologists, S.C. at the Kidney Institute of Wisconsin – Northeast Unit, formed a multidisciplinary team to implement an anemia management CQI program. The program's goals were to improve target Hgb achievement as well as improve the balance between ESA therapy and IV iron therapy as supported by current evidence. Using the key elements of the CQI process, the team established benchmarks for evaluating patient outcomes based on the 2001 National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (K/DOQI) Guidelines (NKF, 2002). A review of patient data revealed that most patients were experiencing high ferritin levels. To determine the next steps, results of several studies on optimal IV iron dosing were evaluated, and established protocols were reviewed, resulting in a simplified IV iron protocol (see Table 1) for the facility. Implementation of the protocol resulted in significant improvements in patient outcomes from March to December 2004, including a decrease in the number of patients with serum ferritins greater than 800 ng/mL and an increase in the percentage reaching target Hgb levels. These improvements occurred despite an increase in the census of patients on hemodialysis (from 116 to 145).

The improvements were attributed to a switch from iron sucrose to sodium ferric gluconate, an increase in patients receiving IV iron therapy with ESA therapy, the consistent adherence to the new protocol, and

the overall improvement in patient care. The team believed other factors that influenced this success included better control of the inflammatory processes and more frequent treatment of iron-restricted erythropoiesis with ESA therapy. The 2004 protocol was successful in meeting the initial CQI program goals, including maintaining satisfactory anemia outcomes in more than 160 patients for more than two years.

2007 CQI Revisions

As part of the CQI process, the anemia management program at the author's facility is subject to an ongoing evaluation by the team to continue to maintain and improve patient outcomes. This ongoing evaluation includes periodic review of the current literature in order to incorporate information from the latest developments in disease management and patient care into the program. Several important developments in 2006 and 2007 led to a revision of the 2004 protocol. The changes made to the protocol are based on the literature review described in Table 1.

Review of the Literature

The 2001 K/DOQI guidelines were revised in 2006 with some changes to treatment targets in patients on hemodialysis who were anemic (NKF, 2002, 2006). In addition to checking Hgb levels, patients with anemia on hemodialysis should undergo periodic assessment of iron status (NKF, 2006). Serum ferritin levels should be used to measure iron stores, and transferrin saturation (TSAT) or reticulocyte Hgb content (CHr) should be used to measure adequacy of iron availability for erythropoiesis. One key difference between the 2001 and 2006 guidelines was the increase in the lower limit for target serum ferritin in patients on hemodialysis, from 100 ng/mL to 200 ng/mL, reflecting new efficacy data for IV iron therapy (NKF, 2002, 2006).

The 2006 KDOQI guidelines also suggested that when interpreting serum ferritin values, it is important to

Table 1
IV Iron Protocol*

Repletion	
2004 Protocol	2007 Revised Protocol (with changes in bold)
TSAT less than 20% and serum ferritin less than 100 ng/mL: • 125 mg IVP over 10 minutes x 8 sessions (1 g). • Draw labs 5 to 7 days post-iron completion: a. If TSAT is still less than 20% and serum ferritin less than 100 ng/mL, then repeat repletion regimen. b. If iron replete, see maintenance protocol.	TSAT less than 20% and serum ferritin less than 200 ng/mL: • 125 mg IVP over 10 minutes x 8 sessions (1 g). • Draw labs 5 to 7 days post-iron completion: a. If TSAT is still less than 20% and serum ferritin less than 200 ng/mL, then repeat repletion regimen. b. If iron replete, see maintenance protocol. For patients with suboptimal response (for example, Hgb less than 11 g/dL) and TSAT less than 20%; serum ferritin greater than 500 ng/mL but less than 1200 ng/mL: • 125 mg IVP over 10 minutes x 8 sessions (1 g).
Maintenance (Patient is achieving target Hgb with current ESA dose)	
2004 Protocol	2007 Revised Protocol (with changes in bold)
TSAT greater than 20% and serum ferritin less than 500 ng/mL: • Administer 62.5 mg IVP over 5 to 7 minutes weekly.	No change
TSAT greater than 20%; serum ferritin greater than 500 but less than 800 ng/mL: • Administer 62.5 mg IVP over 5 to 7 minutes every other week.	TSAT greater than 20%; serum ferritin greater than 500 but less than 1,200 ng/mL: • Administer 62.5 mg IVP over 5-7 minutes every other week
TSAT greater than 20%; serum ferritin greater than 800 ng/mL: • Hold iron for 1 month; reorder serum ferritin and TSAT next month [†] .	TSAT greater than 20%; serum ferritin greater than 1,200 ng/mL: • Hold iron for 1 month; reorder serum ferritin and TSAT next month [†] .
TSAT greater than 50%; serum ferritin at any level: • Notify anemia manager for patient-specific assessment.	No change.

* Presuming that TSATs are ordered monthly and serum ferritins are ordered quarterly.

† KDOQI guidelines recommend holding IV iron for **UP TO** 3 months. If serum ferritin is still above cutoff level after 3 months, notify anemia manager.

Note: If the patient is not achieving target Hgb (11 g/dL) with TSAT greater than 20% and/or serum ferritin greater than 200 ng/mL with an appropriate ESA dose, notify the anemia manager for further assessment.

ESA = erythropoiesis-stimulating agent; Hgb = hemoglobin; IVP = intravenous push; KDOQI = Kidney Disease Outcomes Quality Initiative; TSAT = transferrin saturation.

consider the entire clinical picture, which includes the patient's current clinical status as well as medical history, ESA dose and prior response to ESA, and Hgb values. Serum ferritin is an acute-phase reactant, and these levels may increase during inflammation independently of iron status; therefore, high serum ferritin levels may confound ruling out iron deficiency.

The 2007 update to the K/DOQI guidelines focused specifically on Hgb levels and recommended treating to a target Hgb range of 11.0 to

12.0 g/dL (NKF, 2007). Treating patients in this range results in measurable improvements in quality of life, with little or no increase in adverse events compared with treating to lower Hgb levels.

In March 2007, the U.S. Food and Drug Administration (FDA) issued a black box warning regarding the dosing of ESA in patients with chronic renal failure and anemia (FDA, 2007). The FDA reported that the risks for death and serious cardiovascular events in such patients are greater

when ESA therapy is administered to achieve higher target Hgb levels (13.5 to 14 g/dL) versus lower Hgb levels (10 to 11.3 g/dL). The warning was issued, in part, in response to the publication of data from the Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study (Singh et al., 2006). The CHOIR study showed that using ESAs to treat anemia to a target Hgb of 13.5 g/dL resulted in a significantly increased risk of cardiovascular events or death compared with treating to a target Hgb of 11.3 g/dL.

The results supported recommendations to use lower ESA doses to treat to the lowest Hgb target to avoid increased cardiovascular risk.

Another study, Cardiovascular Risk Reduction by Early Anemia Treatment with Epoetin Beta (CREATE), published in the same issue of *New England Journal of Medicine*, found no increased benefit in cardiovascular outcomes when patients were treated to a target Hgb range of 13.0 to 15.0 g/dL compared with those treated to a target range of 10.5 to 11.5 g/dL (Drüeke et al., 2006). The dosing recommendations for ESA in patients with CKD with anemia were subsequently revised to recommend maintaining Hgb levels within 10 to 12 g/dL.

Also in 2007, findings from the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) study were published (Coyne et al., 2007). In this study, 134 patients on hemodialysis with anemia and with low TSATs (equal to or less than 25%) and high serum ferritins (500 to 1,200 ng/mL) were randomized to receive either IV ferric gluconate or no iron supplementation. Changes from baseline in Hgb response were greater and occurred sooner in the iron supplementation group than in the control group. The magnitude and likelihood of Hgb responsiveness to iron supplementation were unrelated to serum ferritin less than or equal to 800 or greater than 800 ng/mL and baseline TSAT above or below the study median of 19%, indicating that improvement in anemia was not necessarily related to iron status levels in this group of patients.

Revised Protocol

In view of these developments, the 2004 anemia management protocol was revised in late March 2007 to refine ESA dosing and target iron levels without compromising outcomes. Table 1 compares the different protocols described below.

The 2004 protocol at the author's facility was revised to include a cutoff for ESA dosing in response to the FDA black box warning (FDA, 2007), which indicated that ESA dosing should be individualized to achieve and maintain

Hgb levels within the range of 10 to 12 g/dL. In addition, K/DOQI guidelines at that time (NKF, 2006) cautioned against treating to Hgb greater than 13.0 g/dL. Therefore, an Hgb cutoff value of 12.5 g/dL for withholding ESA was added.

The IV iron repletion protocol at the author's facility was revised (see Table 1), and the serum ferritin level for repletion was increased from less than 100 ng/mL to less than 200 ng/mL, according to the new lower limit from the 2006 K/DOQI guidelines (NKF, 2006). The new ESA label does not recommend administering ESA doses if Hgb levels do not increase or reach the recommended range despite appropriate ESA dose titrations over 12 weeks. To comply with the ESA label and improve treatment of poor responders to ESA, the team followed the example of the DRIVE study and treated iron-restricted erythropoiesis in patients with serum ferritin values up to 1,200 ng/mL, using 1 g of iron (up to 125 mg of sodium ferric gluconate given per session for a total of 8 sessions) (Coyne et al., 2007). The maintenance protocol was also revised, increasing the upper limit for serum ferritin from 800 ng/mL to 1,200 ng/mL.

Treating to serum ferritin levels of up to 1,200 ng/mL addresses the common concern of how to treat patients on hemodialysis who have high serum ferritin levels and low TSAT, and who remain anemic despite adequate ESA dosages (Coyne, 2006). Serum ferritin levels are frequently used to assess iron stores in patients on hemodialysis, but they may be an unreliable indicator of iron status (Cavill, 1999; Coyne, 2006). Serum ferritin is a positive acute-phase reactant that is released during inflammatory states. Inflammation is closely linked to protein-energy malnutrition in patients undergoing hemodialysis, and serum ferritin levels are increased in patients with "malnutrition-inflammation complex syndrome," a condition frequently observed in patients on hemodialysis (Kalantar-Zadeh, Rodrigues, & Humphreys, 2004).

In addition, ESA therapy can induce iron-restricted erythropoiesis, a

condition in which iron release from the liver is impaired and iron cannot be delivered to erythroid precursor cells in the bone marrow. During ESA therapy, erythropoiesis is stimulated to supraphysiologic levels with an increased demand for iron. Erythrocyte production initially increases in response to ESA therapy, but Hgb production is not sustained as transferrin-bound iron is depleted. Clinicians may increase ESA doses over time to overcome this apparent resistance to therapy. One must consider that patients with iron-restricted erythropoiesis may have elevated serum ferritin levels as a result of impaired iron metabolism rather than a true lack of iron stores.

The key objective of these protocol changes was to overcome ESA hyporesponsiveness and avoid elevated ESA dosing through proactive treatment of iron-restricted erythropoiesis in patients with serum ferritin less than 1,200 ng/mL. Other objectives were to bring more patients with elevated Hgb into the K/DOQI-recommended Hgb target range without increasing the number of patients with Hgb less than 11 g/dL.

Evaluation: Results of the Protocol Changes

Data from approximately 165 patients in the author's clinic were collected during the three months before and three months after changes in the anemia management protocol were implemented. Increasing the serum ferritin cutoff for withholding IV iron from 800 to 1,200 ng/mL in patients with anemia and low TSAT levels resulted in improvements in several patient outcomes (see Tables 2-6). These improvements included an increased proportion of Hgb laboratory values within the Hgb target range, a decreased proportion of TSAT values less than 20%, and an approximate 25% decrease in average ESA dose.

Within three months of the protocol change, the percentage of Hgb values within the target range of 11.0 to 12.3 g/dL increased by 8% (see Table 2 and Figure 1), while the proportion of Hgb values greater than 12.3 g/dL decreased by the same

Table 2

Hgb Values Before and After Changes in Anemia Management Protocol			Distribution of Hgb Values Before and After Changes in Anemia Management Protocol		
	3 Months Before Changes	3 Months After Changes, g/dL		3 Months Before Changes	3 Months After Changes
Hgb values, <i>n</i>	510	499	Hgb values, <i>n</i>	510	499
Mean	11.9 g/dL	11.8 g/dL	Less than 11	23%	21%
Median	11.9 g/dL	11.9 g/dL	11.0 to 12.3	40%	48%
			Greater than 12.3	38%	30%

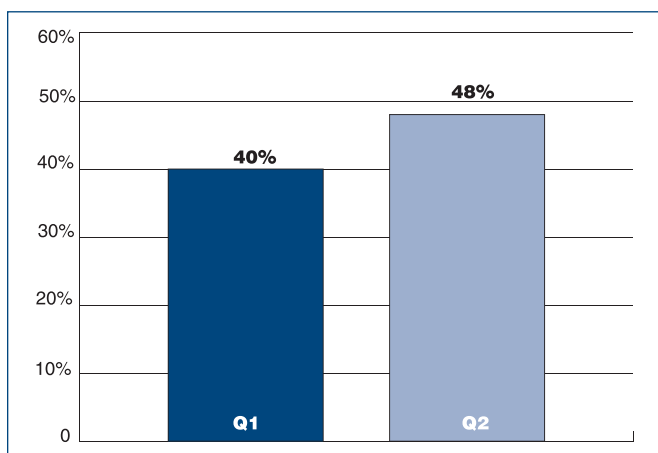
Note: HgB = hemoglobin
Totals may not equal 100% due to rounding.

Table 3

TSAT Values Before and After Protocol Changes			Distribution of TSAT Values, Before and After Protocol Changes		
	3 Months Before Changes, %	3 Months After Changes, %		3 Months Before Changes	3 Months After Changes
TSAT values, <i>n</i>	494	491	TSAT values, <i>n</i>	494	491
Mean	28%	33%	Less than 20%	23%	14%
Median	26%	30%	20% to 50%	72%	75%
			Greater than 50%	5%	11%

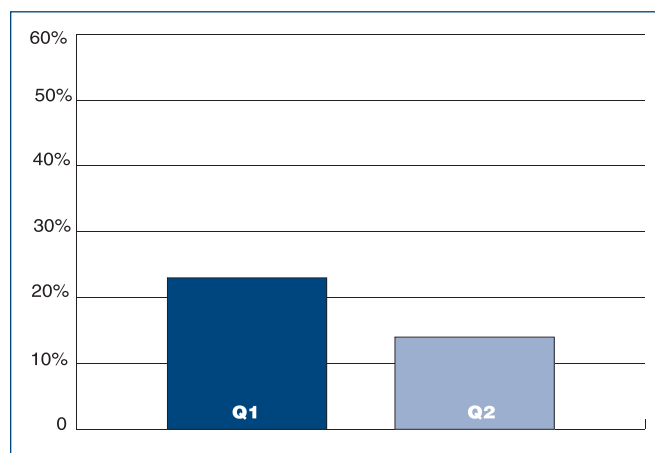
Note: TSAT = transferrin saturation

Figure 1
Percent Hgb Values within Target Range (11 to 12.3 g/dL)



Note: Hgb = hemoglobin; Q1 = 3 months before protocol changes; Q2 = 3 months after protocol changes.

Figure 2
Percent TSAT Values Less Than 20%



Note: TSAT = transferrin saturation; Q1 = 3 months before protocol changes; Q2 = 3 months after protocol changes.

amount. Average monthly Hgb levels were maintained throughout the study.

Mean TSAT levels improved by 5%, and the percentage of TSAT values less than 20% decreased by 9% (see Table 3 and Figure 2). There was an increase in the percentage of

serum ferritin values greater than 800 ng/mL (see Table 4); however, this was expected due to more aggressive treatment of iron-restricted erythropoiesis (see Figure 3). Mean ESA dose decreased by about 25% (see Table 5), while there was no increase in mean IV iron dose (see Table 6).

The incremental improvements in patient outcomes following the protocol changes may be partially attributed to the increase in the serum ferritin cutoff for IV iron administration from 800 to 1,200 ng/mL in patients with anemia with low TSATs. In addition to the DRIVE study results, the hematologic

Table 4

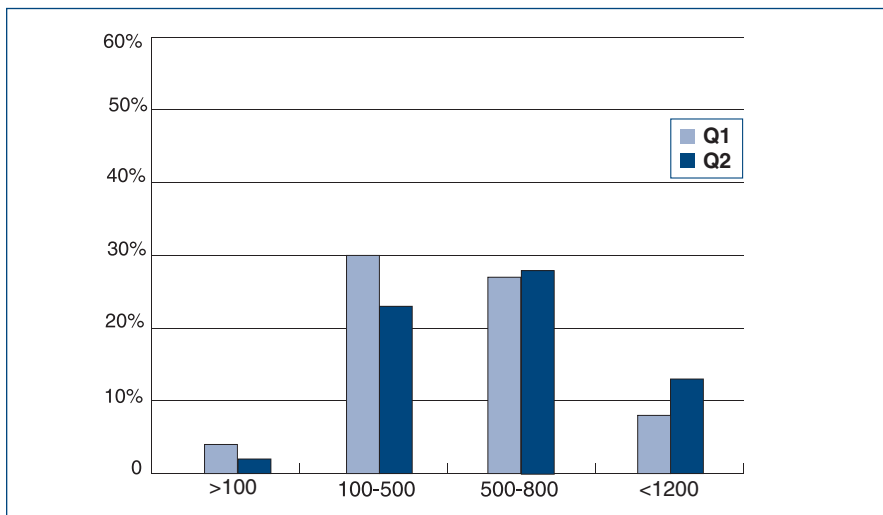
Serum Ferritin Values Before and After Protocol Changes		
	3 Months Before Changes	3 Months After Changes, ng/mL
Serum ferritin values, <i>n</i>	187	170
Mean	691 ng/mL	799 ng/mL
Median	666 ng/mL	796 ng/mL

Distribution of Serum Ferritin Values Before and After Protocol Changes		
	3 Months Before Changes	3 Months After Changes
Serum ferritin values, <i>n</i>	187	170
Less than 100 ng/mL	4%	2%
100 to 500 ng/mL	30%	23%
500 to 800 ng/mL	27%	27%
800 to 1200 ng/mL	30%	35%
Equal to or greater than 1,200 ng/mL	9%	13%

Note: Serum ferritin levels taken quarterly.

Figure 3

Distribution of Serum Ferritin Values Before and After Protocol Changes



Note: Q1 = 3 months before protocol changes; Q2 = 3 months after protocol changes.

Table 5
Monthly ESA Doses Before and After Protocol Changes

ESA ^a Dose	3 Months Before Changes, Units	3 Months After Changes, Units
Mean	67,619	50,179
Median	43,290	36,630

Note: ESA = Erythropoiesis-stimulating agents
^aEpoegen (epoetin alfa), total monthly units.

safety and efficacy of IV iron supplementation in patients with serum ferritin greater than 800 ng/mL and TSAT less than 25% were demonstrated in a study of 95 patients on hemodialysis with anemia and iron-restricted erythropoiesis (Kopelman, Smith, Peoples, Biesecker, & Rizkala, 2007). Patients treated with ESA and sodium ferric gluconate showed a significant increase in Hgb during the three-month study period, whereas patients treated with ESA alone showed a slight but insignificant decrease in Hgb levels. There was no increase in serum ferritin levels in response to IV iron supplementation. Findings provide further evidence that patients with serum ferritin equal to or greater than 800 ng/mL can benefit from IV iron supplementation. In addition, ESA dose requirements may be decreased in these patients.

Overall, the revised protocol continues to meet the program objectives. The protocol change to more aggressive iron replacement resulted in an ESA dose-sparing effect, thus complying with the FDA black box warnings. The decrease in Hgb values greater than 12.3 g/dL was most likely due to the addition of an Hgb cutoff value of 12.5 g/dL for withholding ESA. The percentage of Hgb values within the target range was improved, and anemia outcomes and patient care were not compromised by the protocol change and its revisions. These improvements were achieved with no significant change in the cumulative IV iron dose.

Next Steps: Further Revisions

Patient management protocols, like clinical practice guidelines, need to be reviewed continuously to maintain and improve clinical outcomes. For example, at a subsequent three-month assessment of the CQI program, the protocol was readjusted by increasing the ESA cutoff value for Hgb from greater than 12.5 g/dL to greater than 13.5 g/dL. This increase was in response to the number of patients whose Hgb remained below 10 g/dL. Further review will take place to assess the outcomes based on this change.

Table 6
Monthly IV Iron Supplement Doses Before and After Protocol Changes

IV Iron ^a Dose	3 Months Before Changes	3 Months After Changes
Mean	394 mg	387 mg
Median	312 mg	250 mg

^a Sodium ferric gluconate.

Conclusion

A CQI program provides a framework for review and implementation of improved management strategies and is an important aspect of anemia management programs for patients on hemodialysis. CQI is a continuous process within the dialysis unit that includes evaluation of current outcomes, changes if necessary, and evaluation of the process. One of the hallmarks of CQI is the modification of established protocols in response to updated information and advances in clinical practice. In the author's setting, the CQI process led to the modification of an existing IV iron protocol based on the current literature with subsequent improvements in outcomes, such as better achievement of target Hgb. CQI programs help maintain optimization of patient management protocols while providing a framework for achieving improved patient outcomes.

The CQI process is a fundamental tool in providing overall quality health care. In the future, a CQI program will be a requirement of CMS reimbursement for all outpatient dialysis centers. As part of the implementation of the CQI program at the author's center, the goals are to continue to monitor outcomes of patients on hemodialysis, reassess patient management proto-

cols, and identify additional opportunities for improvement.

References

- Baillie, G.R., Johnson, C.A., & Mason N.A. (2000). Parenteral iron use in the management of anemia in end-stage renal disease patients. *American Journal of Kidney Diseases*, 35, 1-12.
- Besarab, A., Amin, N., Ahsan, M., Vogel, S.E., Zasuwa, G., Frinak, S., et al. (2000). Optimization of epoetin therapy with intravenous iron therapy in hemodialysis patients. *Journal of the American Society of Nephrology*, 11, 530-538.
- Bowe, D., & Ammel, D. (2005). Using CQI strategies to improve and simplify IV iron and anemia management: A dialysis facility's experience. *Nephrology Nursing Journal*, 32, 535-543.
- Cavill, I. (1999). Iron status as measured by serum ferritin: The marker and its limitations. *American Journal of Kidney Diseases*, 34(Suppl 2), S12-S17.
- Centers for Medicaid and Medicare (CMS). (2008). *Medicare and Medicaid programs; Conditions for coverage for end-stage renal disease facilities, final rule. April 15, 2008*. Retrieved June 21, 2008, from <http://www.cms.hhs.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf>
- Chang, C.H., Chang, C.C., & Chiang, S.S. (2002). Reduction in erythropoietin doses by the use of chronic intravenous iron supplementation in iron-replete hemodialysis patients. *Clinical Nephrology*, 57, 136-141.

- Charytan, C., Levin, N., Al-Saloum, M., Hafeez, T., Gagnon, S., & VanWyck, D. (2001). Efficacy and safety of iron sucrose for iron deficiency in patients with dialysis-associated anemia: North American clinical trial. *American Journal of Kidney Diseases*, 37, 300-307.
- Coyne, D. (2006). Iron indices: What do they really mean? *Kidney International*, 69, S4-S8.
- Coyne, D.W., Kapoian, T., Suki, W., Singh, A.K., Moran, J.E., Dahl, N.V., et al. (2007). Ferric gluconate is highly efficacious in anemic hemodialysis patients with high serum ferritin and low transferrin saturation: Results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) study. *Journal of the American Society of Nephrology*, 18, 975-984.
- Dowling, T.C. (2007). Prevalence, etiology, and consequences of anemia and clinical and economic benefits of anemia correction in patients with chronic kidney disease: An overview. *American Journal of Health-System Pharmacy*, 64(13, Suppl 8), S3-S7.
- Drüeke, T.B., Locatelli, F., Clyne, N., Eckardt, K.U., Macdougall, K., Tsikiris, D., et al. (2006). Normalization of hemoglobin level in patients with chronic kidney disease and anemia. *New England Journal of Medicine*, 355, 2071-2084.
- Eschbach, J.W. (1999). Iron therapy and the anemia of ESRD: Historical perspective. *Seminars in Dialysis*, 12, 212-218.
- Gallieni, M. (1998). Iron in the treatment of anemia in dialysis patients: An important support to erythropoietin. *The International Journal of Artificial Organs*, 21, 681-686.
- Gilmartin, C., Na-Thalang, K., Arruda, J., & Lau, A. (2004). Implementing an IV iron maintenance regimen protocol in a hemodialysis practice. *Nephrology Nursing Journal*, 31, 663-671.
- Kalantar-Zadeh, K., Rodrigues, R.A., & Humphreys, M.H. (2004). Association between serum ferritin and measures of inflammation, nutrition and iron in haemodialysis patients. *Nephrology Dialysis Transplantation*, 19, 141-149.
- Kopelman, R.C., Smith, L., Peoples, L., Biesecker, R., & Rizkala, A.R. (2007). Functional iron deficiency in hemodialysis patients with high ferritin. *Hemodialysis International*, 11, 238-246.
- Michael, B., Coyne, D.W., Fishbane, S., Falkert, V., Lynn, R., Nissenson, A.R., et al. (2002). Sodium ferric gluconate complex in hemodialysis patients: Adverse reactions compared to placebo and iron dextran. *Kidney International*, 61, 1830-1839.

Nephrology Nursing Journal Editorial Board Statements of Disclosure

In accordance with ANCC-COA governing rules *Nephrology Nursing Journal* Editorial Board statements of disclosure are published with each CNE offering. The statements of disclosure for this offering are published below.

Paula Dutka, MSN, RN, CNN, disclosed that she is a consultant for Hoffman-La Roche and Coordinator of Clinical Trials for Roche.

Patricia B. McCarley, MSN, RN, NP, disclosed that she is on the Consultant Presenter Bureau for Amgen, Genzyme, and OrthoBiotech. She is also on the Advisory Board for Amgen, Genzyme, and Roche and is the recipient of unrestricted educational grants from OrthoBiotech and Roche.

Holly Fadness McFarland, MSN, RN, CNN, disclosed that she is an employee of DaVita, Inc.

Karen C. Robbins, MS, RN, CNN, disclosed that she is on the Speakers' Bureau for Watson Pharma, Inc.

continued on page 394

IV Iron Therapy

continued from page 377

- Michael, M. (2005). Anemia management protocols: Providing consistent hemoglobin outcomes. *Nephrology Nursing Journal*, 32, 423-426.
- National Kidney Foundation (NKF). (2002). *K/DOQI clinical practice guidelines for chronic kidney disease: Evaluation, classification, and stratification*. Retrieved July 1, 2008, from http://www.kidney.org/Professionals/Kdoqi/guidelines_ckd/toc.htm
- National Kidney Foundation (NKF). (2006). K/DOQI clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease. *American Journal of Kidney Diseases*, 47(Suppl. 3), S1-S146.
- National Kidney Foundation (NKF). (2007). *K/DOQI clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease: 2007 update of hemoglobin target*. Retrieved June 21, 2008, from http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/index.htm.
- Nissenson, A.R., & Strobos, J. (1999). Iron deficiency in patients with renal failure. *Kidney International Supplement*, 69(Suppl.), S18-S21.
- Nissenson, A.R., Lindsay, R.M., Swan, S., Seligman, P., & Shobos, J. (1999). Sodium ferric gluconate complex in sucrose is safe and effective in hemodialysis patients: North American clinical trial. *American Journal of Kidney Diseases*, 33, 471-482.
- Nurko, S. (2006). Anemia in chronic kidney disease: Causes, diagnosis, treatment. *Cleveland Clinic Journal of Medicine*, 73, 289-297.
- Singh, A.K., Szczech, L., Tang, K.L., Barnhart, H., Sapp, S., Wolfson, M., et al., for the CHOIR Investigators. (2006). Correction of anemia with epoetin alfa in chronic kidney disease. *New England Journal of Medicine*, 355, 2085-2098.
- Trenkle, J.A. (2001). Implementing continuous quality improvement strategies for improving iron replacement in hemodialysis patients. *Nephrology Nursing Journal*, 28, 561-565.
- U.S. Food and Drug Administration (FDA). (2007). *Information for healthcare professionals: Erythropoiesis-stimulating agents (ESA)*. FDA alert. Retrieved June 21, 2008, from www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm

Additional Reading

- Hsu, C.Y., McCulloch, C.E., & Curhan, G.C. (2002). Epidemiology of anemia associated with chronic renal insufficiency among adults in the United States: Results from the Third National Health and Nutrition Examination Survey. *Journal of the American Society of Nephrology*, 13, 504-510.

IV Iron Therapy and Anemia Management in Patients on Hemodialysis: Benefits of a Revised CQI Strategy

Deborah Bowe, RN, CNN

Posttest – 1.4 Contact Hours

Posttest Questions

(See posttest instructions on the answer form, on page 379.)

1. **Anemia occurs in approximately what percent of patients with Stage 4 chronic kidney disease?**
 - a. 25%
 - b. 30%
 - c. 40%
 - d. 50%
2. **The potential adverse effects of anemia in patients undergoing hemodialysis include which of the following?**
 - a. The need for erythropoiesis-stimulating agents (ESAs)
 - b. Poor cardiovascular outcomes
 - c. Increased risk of neurologic disorders
 - d. Hyperresponsiveness to ESA therapy
3. **Iron supplementation is an important adjunct to ESA therapy in patients on hemodialysis with anemia. Which of the following is the preferred route of administration for replenishing iron stores in this patient population?**
 - a. Iron supplementation with oral iron tablets
 - b. Increasing the dietary content of iron-rich foods
 - c. Intravenous (IV) iron supplementation
 - d. Intramuscular iron supplementation
4. **According to the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI), hemoglobin (Hgb) testing should be accompanied by evaluation of iron stores. Which of the following laboratory values reflects KDOQI recommendations for testing iron availability?**
 - a. Serum ferritin level
 - b. Transferrin saturation (TSAT)
 - c. Serum iron level
 - d. Plasma iron level
5. **The 2006 KDOQI guidelines suggest which of the following considerations when interpreting serum ferritin values?**
 - a. Careful evaluation of the patient's clinical status, medical history, current ESA dose and previous response to ESA therapy, in addition to Hgb levels.
 - b. Complete cardiovascular workup with immediate lowering of iron and ESA doses.
 - c. Patients with serum ferritin levels greater than 500 ng/mL should not receive combined ESA and IV iron therapy.
 - d. Patients with serum ferritin levels greater than 800 ng/mL should not receive combined ESA and IV iron therapy.
6. **Continuous Quality Improvement (CQI) includes regular monitoring and evaluation of data and trends with the aim of improving patient outcomes. In the management of anemia in patients undergoing hemodialysis, a primary aim of a CQI program is to:**
 - a. Provide a standardized way to achieve and maintain target Hgb levels
 - b. Allow for hemodialysis staff performance evaluations
 - c. Encourage individualized hemodialysis-unit definitions of Hgb targets and need for iron
 - d. Meet standards of care as required by the Centers of Medicare & Medicaid (CMS)
7. **Results of the Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study, published in 2006, resulted in which of the following recommendations for dialysis patients?**
 - a. Initiating IV iron therapy to improve Hgb levels
 - b. Using lower ESA doses to treat to a target Hgb of 11.3 g/dL
 - c. Stopping ESA therapy in patients with Hgb levels greater than 12.0 g/dL
 - d. Administration of blood transfusions more often to correct anemia
8. **The Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) study showed that patients with high serum ferritin levels (500-1200 ng/mL) and low TSATs (equal to or less than 25%) had better outcomes when they received which of the following?**
 - a. No ESA therapy
 - b. No IV iron therapy
 - c. IV iron therapy
 - d. Oral iron therapy
9. **This anemia management team updated the CQI protocol at their institution based on CHOIR and DRIVE results. Which of the following changes did they determine as key to better anemia outcomes?**
 - a. Increasing the serum ferritin cutoff value from 800 ng/mL to 1200 ng/mL
 - b. Maintaining the ESA dose at an Hgb cutoff value of 12 g/dL
 - c. Adjusting ESA doses to maintain target Hgb levels less than 11 g/dL
 - d. Adjusting IV iron therapy according to TSAT levels
10. **CQI programs such as the one described in this article:**
 - a. Will soon be required by the CMS
 - b. Are required for licensure of inpatient and outpatient dialysis centers
 - c. Should be evaluated annually, with protocol updates once yearly
 - d. Are currently recommended in the most recent KDOQI guidelines

ANNJ0811

ANSWER/EVALUATION FORM

IV Iron Therapy and Anemia Management in Patients on Hemodialysis: Benefits of a Revised CQI Strategy

Deborah Bowe, RN, CNN

1.4 Contact Hours
Expires: August 31, 2010
ANNA Member Price: \$15
Regular Price: \$25

Posttest Instructions

- Select the best answer and circle the appropriate letter on the answer grid below.
- Complete the evaluation.
- Send only the answer form to the ANNA National Office; East Holly Avenue Box 56; Pitman, NJ 08071-0056; or fax this form to (856) 589-7463.
- Enclose a check or money order payable to ANNA. Fees listed in payment section.
- If you receive a passing score of 70% or better, a certificate for the contact hours will be awarded by ANNA.
- Please allow 2-3 weeks for processing. You may submit multiple answer forms in one mailing, however, because of various processing procedures for each answer form, you may not receive all of your certificates returned in one mailing.

Complete the Following:

Name: _____

Address: _____

Telephone: _____ Email: _____

CNN: ___ Yes ___ No **CDN:** ___ Yes ___ No **CCHT:** ___ Yes ___ No

Payment:

ANNA Member: ___ Yes ___ No Member # _____

Check Enclosed American Express Visa MasterCard

Total Amount Submitted: _____

Credit Card Number: _____ Exp. Date: _____

Name as it Appears on the Card: _____

Special Note

Your posttest can be processed in 1 week for an additional rush charge of \$5.00.
 Yes, I would like this posttest rush processed. I have included an additional fee of \$5.00 for rush processing.

Submit
Online!

Online submissions through a partnership with HDCN.com are accepted on this posttest at \$20 for ANNA members and \$30 for nonmembers. CNE certificates will be available immediately upon successful completion of the posttest.

Note: If you wish to keep the journal intact, you may photocopy the answer sheet or access this posttest at www.annanurse.org/journal

Posttest Answer Grid (Please circle your answer choice):

- | | | | | |
|------------|------------|------------|------------|-------------|
| 1. a b c d | 3. a b c d | 5. a b c d | 7. a b c d | 9. a b c d |
| 2. a b c d | 4. a b c d | 6. a b c d | 8. a b c d | 10. a b c d |

Evaluation	Strongly disagree	1	2	3	4	Strongly agree
1. The objectives were related to the goal.	1	2	3	4	5	
2. Objectives were met						
a. Describe the revision of an anemia management protocol in the context of an established CQI process.	1	2	3	4	5	
b. Explain how evidence-based literature on erythropoietin-stimulating agents and IV iron therapy should be used to drive CQI revision.	1	2	3	4	5	
c. Evaluate the effects on patient outcomes of a revised anemia management protocol using the CQI process.	1	2	3	4	5	
3. The content was current and relevant.	1	2	3	4	5	
4. This was an effective method to learn this content.	1	2	3	4	5	
5. Time required to complete reading assignment: _____ minutes.						

GOAL To illustrate how the successive use of a continuous quality improvement program for maintaining and improving an intravenous iron and anemia management protocol can improve patient outcomes.

I verify that I have completed this activity:

(Signature)

Comments _____

Suggested topics for future articles? _____