

Using CQI Strategies to Improve and Simplify IV Iron and Anemia Management: A Dialysis Facility's Experience

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Over the past decade, significant advancements have been made in the treatment of iron-deficiency anemia in patients with chronic kidney disease (CKD) and end stage renal disease (ESRD), including the introduction of non-dextran intravenous (IV) iron therapy and the development of the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (K/DOQI™). However, the most recent statistics show that anemia remains inadequately managed in hemodialysis patients. Based on a random sample during a 3-month period, 21% of incenter hemodialysis patients were not achieving the K/DOQI-recommended target Hgb level of 11 to 12 g/dL and 20% of patients had transferrin saturation (TSAT) levels below the iron-replete range (2003 ESRD CPM annual report). Therefore, in an effort to further advance outcomes in this patient population, it is important for the nephrology community to address iron-deficiency anemia more aggressively. One approach is to establish an IV iron protocol that includes early evaluation of iron status and maintenance iron dosing to

Intravenous (IV) iron therapy has been proven to be effective in managing anemia and improving iron parameters in hemodialysis patients. However, despite the benefits of IV iron therapy, anemia remains underrecognized and undertreated, with many hemodialysis patients not achieving target hemoglobin (Hgb) levels. Although the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative has increased the clinician's focus on iron deficiency, there are still opportunities available to ensure that all patients are being managed correctly. One such opportunity is the establishment of a maintenance IV iron protocol as an integral part of anemia management. The development and implementation of an IV iron protocol can help stabilize Hgb levels, optimize recombinant human erythropoietin and iron dosing, and simplify the entire iron and anemia management process.

Goal

To describe how to improve outcomes with the development and implementation of a simplified IV iron and anemia management protocol.

Objectives

1. Discuss the importance of iron in treatment of anemia.
2. Examine how a dialysis facility used a CQI program to develop and implement an IV iron protocol.
3. Identify practical strategies to help initiate an iron protocol and improve outcomes.

prevent the recurrence of iron deficiency and help manage anemia. Fortunately, the development and implementation of an iron protocol is not a difficult process, and the protocol itself can be easy to follow and will help simplify the entire dialysis experience. The use of a continuous quality improvement (CQI) program can help clinicians initiate an iron protocol and help improve outcomes in hemodialysis patients with iron-deficiency anemia.

Importance of Iron in Anemia Management

Before learning how CQI strategies can be used to develop a simplified IV iron and anemia management protocol, the nephrology nurse should understand the importance of iron therapy in effective erythropoiesis. Despite the use of recombi-

nant human erythropoietin (EPO) therapy, the prevalence of anemia continues to be high in hemodialysis patients because EPO therapy satisfies only one part of the hemoglobin (Hgb)-building equation. In order to ensure healthy red blood cell (RBC) production, the body also requires sufficient iron stores. Although erythropoietin is important in the initial phase of RBC development, iron is essential in the latter phase, as Hgb is incorporated into reticulocytes and released into the circulation as mature RBCs. Insufficient iron supplies at these later stages can result in small RBCs with inadequate oxygen-carrying capacity (Brock, 1994).

Patients with CKD, particularly those on hemodialysis, often lack adequate iron stores due to blood loss resulting from frequent laboratory tests, dialysis-related procedures, and gastrointestinal bleed-

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ing (K/DOQI, 2001; Sakiewicz et al, 1998; Eschbach, 1999). In addition, acute and chronic inflammatory conditions can interfere with the body's ability to access iron stores.

If left untreated, anemia can result in numerous adverse outcomes, including reduced quality of life, impairments in cognitive functioning, and cardiovascular abnormalities, such as increased left ventricular hypertrophy (Horwich et al., 2002; Ludwig et al., 2001).

According to the K/DOQI guidelines, the combination of IV iron and EPO therapy is an effective strategy for bringing patients within the recommended Hgb levels of 11 to 12 g/dL, and most hemodialysis patients will require maintenance IV iron therapy to stabilize their target Hgb levels (K/DOQI, 2001). Multiple studies also have documented that IV iron with EPO offers added clinical benefits, such as accelerated Hgb production in patients with CKD (Panesar et al., 2002), higher Hgb levels compared to oral iron plus EPO in hemodialysis patients (Nissenson et al., 1999), and improved erythropoiesis as measured by reduced EPO dosing requirements in hemodialysis patients (Chang et al., 2002; Besarab et al., 2000).

In addition, IV iron can correct absolute iron deficiency (in which the body lacks sufficient iron stores) and functional iron deficiency (in which EPO-induced erythropoiesis consumes circulating iron faster than the body can release stored iron) (K/DOQI, 2001). These benefits of IV iron therapy can be achieved with the use of an effective iron maintenance protocol, which can be easily implemented using a CQI program.

What Is a CQI Program?

A CQI program is a philosophy of management that requires members of a team to regularly monitor patient data and trends and evaluate and update processes to produce better outcomes (Trenkle, 2001). Some key

strategies of a CQI program are to (1) organize a management team, (2) benchmark current processes, (3) identify opportunities for improvement, (4) initiate a plan of intervention, (5) evaluate the results, and (6) revise the plan as necessary. In a nurse-driven CQI process, the nurse manages the activities and movement of a CQI program and involves the physicians in progress updates and the approval process of implementing change.

Benefits of a CQI Program

Although implementing a CQI program requires commitment, motivation, organization, and focus, the team can expect many rewards in return for their efforts. One benefit of a CQI program is *improved outcomes*. A CQI program enables the team to identify poor responders to current therapies and determine if different interventions can provide better outcomes. This may include switching IV iron therapies to help patients maintain target serum ferritin levels or to help avoid adverse reactions, such as converting from an iron dextran to a non-dextran iron to avoid anaphylactoid reactions. A CQI process also will enable the team to identify and revise protocols that are not working.

Another benefit of the CQI process is *enhanced patient safety*. A CQI program can prevent deviations from standard practices, thereby enhancing patient safety and avoiding errors, which can particularly occur in a busy clinic. Using CQI strategies, the team can develop an easy-to-follow protocol for treating adverse reactions or avoiding infection. The protocol also can include routine measurement and recording of iron levels to help the hemodialysis unit track the efficacy and safety record of particular IV iron products.

A CQI program can lead to *increased patient satisfaction*. As patients reach target Hgb and iron levels, they will experience decreased hospitalization, increased

energy, and improved quality of life (Churchill et al., 1995; Evans et al., 1990; Lim, 1991). These improvements in well-being will result in enhanced patient satisfaction with the overall hemodialysis experience and greater confidence in the health care team.

Implementing a CQI program can result in *reduced variability in practice*. A key component of CQI is to provide consistency in the way care is delivered to patients. CQI strategies can help clinicians ensure treatment options consistent with K/DOQI recommendations and enable the staff to respond in a consistent manner to challenging cases, such as EPO hyporesponse due to iron deficiency, recurrent infections, and abnormal laboratory values.

A CQI program can *reduce costs and wastage and increase unit revenue*. By optimizing IV iron use, a CQI program can help reduce costs, such as those associated with EPO therapy and morbidity treatment. In addition, it can help reduce hospitalization, which means more outpatient treatments and less revenue lost when hospitalization occurs. CQI strategies also can help institute cost-effective approaches to care, such as developing a maintenance IV iron protocol to avoid fluctuating Hgb and hematocrit levels and effectively administer iron without wastage.

Finally, a CQI program can *decrease problems with reimbursement and increase payment with proper documentation*. Clinicians can apply CQI principles to develop a standard of care that will lead to better outcomes and help prove the clinical benefit of a drug. This is important as the Centers for Medicare and Medicaid Services increases its focus on requiring dialysis facilities to demonstrate a stronger association between an intervention and the clinical benefit in order to receive reimbursement. Also, proper documentation of lab values, medications, and interventions will lead to the submission of consistent information and appropriate reimbursement.



Figure 1
Simplified IV Iron Protocol*

Repletion

1.	TSAT <20% and serum ferritin <100 ng/mL	<ul style="list-style-type: none"> • Administer 125 mg IVP over 10 minutes x 8 sessions (1 g) • Draw labs 5-7 days post-iron course completion: <ul style="list-style-type: none"> A. If still TSAT <20% and serum ferritin <100 ng/mL, then repeat repletion regimen B. If iron replete, see action steps 2-4
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Maintenance (Patient is achieving target Hgb with current EPO dose)

	TSAT	Serum Ferritin	Recommendation
2.	>20%	<500 ng/mL	• Administer 62.5 mg IVP over 5-7 minutes weekly
3.	>20%	>500 but <800 ng/mL	• Administer 62.5 mg IVP over 5-7 minutes every other week
4.	>20%	>800 ng/mL	• Hold iron for 1 month and reorder serum ferritin and TSAT next month [†]
5.	>50%	Any level	• Notify anemia manager for patient-specific assessment

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

[†]K/DOQI recommends holding IV iron for **UP TO** 3 months. If serum ferritin is still >800 ng/mL after 3 months, notify anemia manager.

NOTE: If the patient is NOT achieving target Hgb (11 g/dL) with iron values greater than TSAT 20% and/or serum ferritin >100 ng/mL with an appropriate EPO dose, notify the anemia manager for further assessment.

EPO = recombinant human erythropoietin; Hgb = hemoglobin; IVP = intravenous push; K/DOQI = Kidney Disease Outcomes Quality Initiative; TSAT = transferrin saturation.

The CQI Process in Action: A Dialysis Facility's Experience

The Milwaukee Nephrologists, S.C. at the Kidney Institute of Wisconsin – Northeast Unit is an outpatient dialysis center with a staff of 6 attending physicians, 10 nurses, 1 dietician, and 1 clinical pharmacist, all of whom currently treat approximately 150 patients on hemodialysis. In a continuing effort to improve patient care, staff efficiency, and product utilization, the facility formed an anemia management team to implement a CQI program in the spring of 2004. The team was headed by a physician with an interest in anemia and iron and consisted of the clinical administrator, anemia manager, social worker, dietician, and pharmacist.

Utilizing the CQI process, the

team examined the facility's current IV iron environment and found opportunities for improvement. Upon review of the unit's patient data trends, they noticed that the majority of patients were experiencing high serum ferritin levels and determined a change was needed in their IV iron management process.

After consulting with various personnel and reviewing current literature, the team decided to switch from iron sucrose to sodium ferric gluconate, which has been proven effective as maintenance therapy. Because the facility was changing interventions, the management team also decided it was important to provide educational services about sodium ferric gluconate and revise their IV iron protocol. Prior to implementing any changes, though, the team established the following pre-

liminary goals:

1. Decrease the percentage of patients with serum ferritin >800 ng/mL.
2. Simplify (or at least do not further complicate) the iron management process.
3. Increase and maintain the number of patients achieving target Hgb levels.
4. Improve the balance of EPO and IV iron therapy.

Developing a Simplified IV Iron Protocol

Subsequent to carrying out the initial stages of the CQI process, the team was ready to develop a plan of intervention. After deciding to implement a simplified protocol using sodium ferric gluconate, they consulted various sources for identifying optimal dosage parameters. One study

showed that the mean IV iron maintenance dose required to maintain a serum ferritin level of 500 ng/mL was approximately 60 mg/week and that greater mean doses (up to 100 mg/week) were necessary only to increase the serum ferritin level at the beginning of an iron protocol (Richardson et al., 2001).

The team also reviewed 2 analyses to help determine an appropriate dosage. One retrospective analysis showed that the average hemodialysis patient receives between 60 and 64 mg of IV iron weekly, regardless of product or protocol (Schmidt et al., 2005). Another analysis demonstrated that IV iron 125 mg monthly (62.5 mg every other week) or 125 mg twice monthly (62.5 mg weekly) resulted in steady iron levels, EPO doses, and Hgb values (Gilmartin, 2004).

In addition, the team learned that, according to the K/DOQI guidelines, hemodialysis patients will need approximately 1 to 3 g of iron annually to meet the demands of RBC production and ongoing blood loss. Therefore, if maintenance IV iron is dosed at 62.5 mg, the patient will receive between 3.25 g (62.5 mg x 52 weeks) and about 1.6 g (62.5 mg x 26 weeks) of IV iron annually, which is within K/DOQI guidelines (the amount of iron will be less if iron is held).

Based on these resources, the team determined that sodium ferric gluconate, which is available as a single-dose ampule containing 62.5 mg of iron, offers a practical dosing option for maintenance therapy. In addition, an entire 62.5 mg ampule of sodium ferric gluconate can be administered effectively without wastage.

After evaluating the literature on optimal dosage levels and reviewing established protocols, the team developed their protocol based on the most compelling aspects of the researched sources. One of these resources focused on a simple protocol for nurses and 2 general assessment guidelines for anemia managers. The protocol (see Figure 1) is

a simplified version of an IV iron protocol that can be easily implemented by staff members, thereby simplifying the entire dialysis process. The interventional supplement (see Figure 2) is used by the anemia manager to consistently assess patients who are not achieving an Hgb >11 g/dL, despite IV iron and EPO therapy. The triage supplement (see Figure 3) is used if the anemia manager is uncomfortable with immediately using the interventional recommendations or if the patient has had multiple complications or had been treated for functional iron deficiency with no improvement. This supplement can help rule out underlying causes of inflammation and infection, improve and standardize overall care, and enhance staff time utilization (ie, decrease unnecessary labs, iron/EPO dosing changes, and confusion).

It is important to note that implementing these protocols is not an enormous undertaking, but rather a simple process that can result in improved patient care and outcomes. Because most protocols are about 70% to 80% effective, with only about 20% to 30% of patients not falling within the standard protocol, it can be ascertained that this is an easy-to-follow process for the majority of the patients and only about 20% of them will need to be triaged with the supplemental protocols. Although at first review this process may appear complicated, one of its advantages is its simplicity of use.

Assessing the Impact of the Revised IV Iron Protocol

As part of the final stages of the CQI process, the team assessed the impact of the revised protocol and determined if their objectives had been accomplished. Although patient outcomes have improved after the conversion to sodium ferric gluconate, the team recognized that this initiative was not intended to be a scientific study, making it difficult to identify the exact reasons for the improvement.

Upon evaluation of the protocol's impact, the team noted the average serum ferritin level decreased from 1044 ng/mL with iron sucrose in March to 624 ng/mL with sodium ferric gluconate in December (see Table 1). In addition, the percentage of patients with a serum ferritin level >800 ng/mL decreased from approximately 64% with iron sucrose in March to approximately 29% with sodium ferric gluconate in December. More importantly, however, is the fact that as IV iron was administered more frequently (in up to 67% of patients), the average serum ferritin level remained <800 ng/mL. All of these improvements occurred despite an increase in census of dialysis patients from 116 to 145. Most incoming patients were new to dialysis and were not on pre-dialysis EPO therapy.

The team attributed the decrease in serum ferritin levels to the conversion from iron sucrose to sodium ferric gluconate. They suggested that sodium ferric gluconate may have caused a smaller inflammatory increase in serum ferritin and that sodium ferric gluconate 62.5 mg weekly or every other week offered better control of serum ferritin levels than iron sucrose 50 or 100 mg weekly. Other reasons suggested by the team were that iron dosing was reduced when serum ferritin was >500 ng/mL and the improvement in overall patient care helped to decrease the amount of serum ferritin reflecting inflammation.

Further review showed that the percentage of patients with Hgb >11 g/dL increased from 76% with iron sucrose in May to 86% with sodium ferric gluconate in December (see Table 2). The team proposed that the improved Hgb response was due to the use of sodium ferric gluconate, the steady increase in the percentage of patients receiving IV iron, and the unit's consistent adherence to the new iron protocol. The team also suggested that the increase in patients achieving target Hgb levels could be attributed to the more aggressive treatment of inflammato-



Figure 2
Anemia Manager Intervention Recommendations

If patient is on maintenance IV iron and steady EPO but NOT achieving Hgb >11 g/dL:

	TSAT	Serum Ferritin	Potential Intervention
1.	<20% and	>100 & <500 ng/mL	A. Rule out functional/absolute ¹ iron deficiency and administer 125 mg IVP over 10 minutes x 4-8 sessions (500 mg-1 g, respectively)
2.	<20% and	>500 & <800 ng/mL	<ul style="list-style-type: none"> • Evaluate current EPO dose and reorder serum ferritin next month. If the serum ferritin does not decrease that next month and patient fails to meet Hgb target, see recommendations for action steps A, B, or C: A. Rule out functional/absolute¹ iron deficiency and administer 125 mg IVP over 10 minutes x 4-8 sessions (500 mg-1 g, respectively) B. Assess patient for infection/inflammation, elevated PTH, or other cause of EPO hyporesponse. Possibly order a CRP C. Evaluate EPO dose and query patient for possible bleeding
3.	<20% and	>800 ng/mL	B. Assess patient for infection/inflammation, elevated PTH, or other cause of EPO hyporesponse. Possibly order a CRP. If no solution can be found, then evaluate current EPO dose
4.	>20% and	>100 & <500 ng/mL	<ul style="list-style-type: none"> • Evaluate recent iron dose. Possible functional iron deficiency (see action step A). Has iron been held in recent months? If so, IV iron may again be of benefit. A. Rule out functional/absolute¹ iron deficiency and administer 125 mg IVP over 10 minutes x 4-8 sessions (500 mg-1 g, respectively)
5.	>20% and	>500 & <800 ng/mL	C. Evaluate EPO dose and query patient for possible bleeding. If no solution, review recent iron administration
6.	<20% and	>800 ng/mL for 3 months*	<ul style="list-style-type: none"> • Requires MD intervention. See action steps A, B, or C: A. Rule out functional/absolute¹ iron deficiency and administer 125 mg IVP over 10 minutes x 4-8 sessions (500 mg-1 g, respectively) B. Assess patient for infection/inflammation, elevated PTH, or other cause of EPO hyporesponse. Possibly order a CRP C. Evaluate EPO dose and query patient for possible bleeding
7.	>50%		<ul style="list-style-type: none"> • Evaluate EPO dose and any recent changes, assess lab trends, check patient's nutritional status, assess recent iron administration, and possibly reorder iron measures to rule out lab error. Look at lab trending and recent iron dosing

*K/DOQI recommends holding IV iron for **UP TO** 3 months.

NOTE: Recommendations 1-7 are starting points. Evaluate all aspects of patient's care and trend labs over time to appropriately assess lack of EPO efficacy. If patients do not fit these categories or interventions are ineffective, consult attending MD.

CRP = C-reactive protein; EPO = recombinant human erythropoietin; Hgb = hemoglobin; IVP = intravenous push; K/DOQI = Kidney Disease Outcomes Quality Initiative; PTH = parathyroid hormone; TSAT = transferrin saturation.

1. National Kidney Foundation (2001). *American Journal of Kidney Diseases*, 37(suppl), S194-S206.

Figure 3
Triage Checklist for Ruling Out Inflammation/Infection and Causes of EPO Hyporesponse

A. Serum ferritin is an acute-phase reactant and is elevated during inflammation and infection. Clinicians should look for acute exacerbations of the following common causes of inflammation and infection in hemodialysis patients:

Inflammation ¹	Infection ¹
Dialysis	Access site (catheter)
Diabetic skin ulcer	Urinary tract infection
Arthritis	Wound
Cellulitis	Abscessed teeth
Surgery	Pneumonia
Gout	Hepatitis B and C

Patient-Specific Anemia Analysis Methodology

- A. Patient presentation? What is different? What else could be causing inflammation? _____
 B. Look at the last 3 quarterly/monthly TSAT and serum ferritin levels to assess a trend.

Date				
Serum Ferritin				
TSAT				

- C. When was IV iron last administered and how much? _____
 K/DOQI recommends 1-3 g per year.² How much IV iron has the patient received in the last:
 Month? _____ Quarter? _____ Year? _____

Example: If serum ferritin is rising without IV iron, it is not likely a true measure of iron status. Has the patient gone 3 months without IV iron, yet serum ferritin is still elevated? If so, it is not likely due to iron overload.

- D. **Functional Iron Deficiency?** Consult MD about administration of 1 g of IV iron over 8-10 weeks. If Hgb improves or EPO needs decrease, the patient probably had functional iron deficiency. If not, rule out other possible causes of infection and inflammation.²
 E. **Rule out inflammation and infection.** Consult MD about ordering a CRP. CRP levels in hemodialysis patients are normally 10-20 mg/L (value for standard CRP); >20 mg/L usually indicates an inflammatory state.^{3,4} A high CRP can affirm you should look for some underlying inflammation. Think of all potential causes of inflammation and try to resolve that condition.
 F. **Some additional questions to consider when assessing anemic patients:**

Recent hospitalization or surgery? _____	Unreliable patient compliance and disclosure? Consider social worker consult or dietary consult Possible lab error? _____ Bone disease? ² _____ Aluminum toxicity? ² _____ Nonfunctioning arteriovenous grafts or rejected transplants? These can harbor undiagnosed infections/inflammation and decrease EPO efficacy ^{5,6} Is patient a smoker? Do they have undiagnosed asthma or emphysema or cancer? _____ Check medication compliance for untreated underlying inflammatory conditions _____
Catheter or any change in access? _____	
GI bleed? Access bleeding? _____	
Low albumin, prealbumin, transferrin? Possible malnutrition? _____	
Has patient been tested for HIV? Autoimmune diseases? _____	
Co-existing medical conditions? Inflammatory diseases exacerbated? _____	

CRP = C-reactive protein; EPO = recombinant human erythropoietin; Hgb = hemoglobin; K/DOQI = Kidney Disease Outcomes Quality Initiative; TSAT = transferrin saturation.

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6. Lopez-Gomez J.M. et al. (2004). *Journal of the American Society of Nephrology*, 15, 2494-2501.



ry processes (which can lead to blockage of iron stores and EPO hyporesponse), more frequent treatment of functional iron deficiency, and a better overall focus on anemia management. In addition, the CQI data showed that the most frequent causes of low Hgb levels and lack of EPO response were infections and surgery. However, prior to early 2004, the most cited cause was iron deficiency (defined as TSAT <20% and serum ferritin <300 ng/mL).

In addition, the team assessed if the balance of EPO and IV iron therapy had been improved (see Table 2). After reaching a point in May when approximately 67% of patients were not receiving IV iron to a high monthly EPO dose in September of 85,113 IU, the balance of IV iron and EPO leveled off in December with approximately 67% of the patients receiving a median of

Table 1
Serum Ferritin Levels

Serum Ferritin, ng/mL	Iron Sucrose		Sodium Ferric Gluconate	
	Mar-04	Jun-04	Sep-04	Dec-04
Average	1044	737	664	624
Median	1015	693	571	534
% of Patients	Mar-04	Jun-04	Sep-04	Dec-04
<100 ng/mL	2.56%	4.84%	3.47%	2.74%
>800 ng/mL	64.10%	40.32%	31.25%	28.77%

sodium ferric gluconate 250 mg/month and a monthly EPO dose of 66,239 IU. By adhering to maintenance treatment, rather than repletion therapy (i.e., stopping and starting iron), the team was able to stabilize Hgb levels, iron dosing, and EPO dosing.

Finally, preliminary feedback has shown that the new protocol is not

more complicated than previous protocols. In fact, it has been suggested that the iron management process has been easier, considering that, during this period, the patient population has increased by 34% and the percentage of patients with Hgb levels >11 g/dL has increased by 10% with the use of sodium ferric gluconate.

Table 2
Impact of IV Iron Protocol

	Iron Sucrose					Both	Sodium Ferric Gluconate					
	Jan-04	Feb-04	Mar-04	Apr-04	May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04
% Pts With Hgb <11 g/dL	19%	21%	25%	21%	24%	21%	13%	24%	33%	23%	20%	14%
% Pts With Hgb >11 g/dL	81%	79%	75%	79%	76%	79%	87%	76%	67%	77%	80%	86%
Average IV Iron Dose, mg/month	573	397	216	167	243	327.3	373.1	372.0	367.2	348.1	320.1	297.7
Median IV Iron Dose, mg/month	400	400	100	100	125	212.5	250	250	312.5	250	187.5	250
Median IV Iron Dose, mg/week	100	100	25	25	31.25	50	62.5	62.5	62.5	62.5	62.5	62.5
Average EPO Dose, U/month	66,196	59,273	68,278	64,675	67,926	69,788	71,783	76,885	85,113	83,308	74,389	66,239
Average EPO Dose, U/week	16,549	14,818	17,070	16,169	16,982	17,447	17,946	19,221	21,278	20,827	18,597	16,560
% Pts on IV Iron	73.15%	77.39%	75.42%	35.45%	32.76%	35.20%	40.16%	47.33%	55.56%	54.48%	64.08%	66.90%
No. of Pts	108	115	118	110	116	125	127	131	144	145	142	145

EPO = recombinant human erythropoietin; Hgb = hemoglobin; IV = intravenous

Next Steps

Although the team concluded that their goals had been achieved and the project was a success, the CQI process requires that the current trend be maintained and improved. In order to do this, the team will continually review their processes and make revisions as needed. Their next steps are to:

- Continue to monitor outcomes and implement a more effective triage tool for troubleshooting patients with elevated serum ferritin levels, exorbitant EPO doses, and sub-therapeutic Hgb levels. The goal will be to effectively manage staff time and further increase the percentage of patients achieving target Hgb levels.
- Discuss potential tools to monitor anemia manager compliance with the new protocol from clinic to clinic.
- Determine a process to better evaluate previously identified data that may warrant a deeper analysis.
- Establish a plan of action for how to communicate this information and process to other anemia managers in order to assist more patients.

Practical Strategies for Developing an Iron Protocol

An appropriate IV iron protocol should simplify the entire treatment process and emphasize the importance of maintenance therapy as a proactive step in preventing the recurrence of iron deficiency and helping to manage anemia. The following suggestions can help a dialysis unit successfully facilitate the adoption of an iron maintenance program.

Strategy #1

When looking for opportunities to improve current processes, an anemia management team can track patient data trends; review literature and published standards of care; analyze national, state, and network trends;

and evaluate patient satisfaction with the hemodialysis experience. Essentially, the facility should look for high-volume problems, such as a high percentage of patients who are hyporesponsive to EPO therapy due to iron deficiency.

Strategy #2

Prior to developing the protocol, it is important to identify factors that may influence the facility's decision to introduce an IV iron therapy or switch IV iron products as part of managing anemia. Some members of the medical staff may be unwilling to administer IV iron on a regular schedule or be unfamiliar with the benefits of IV iron. Therefore, when the anemia management team meets to discuss possible revisions to the protocol, it may be necessary to refer to the literature to validate the effectiveness and benefits of maintenance iron therapy.

Strategy #3

During an analysis of a unit's current processes and patient outcomes, the team should consider the following:

- How does the current protocol compare with the K/DOQI recommendations of using maintenance iron therapy to sustain target lab values?
- What target lab values are being used to indicate the starting and stopping of iron? How does this compare with the K/DOQI-recommended targets of TSAT 20% to 50% and serum ferritin 100 to 800 ng/mL?
- Do patients have high serum ferritin levels due to an inflammatory process or is it iron related?
- How are patients with absolute iron deficiency, functional iron deficiency, or inflammatory blockade being treated? Are staff members able to differentiate between these conditions?

Strategy #4

To facilitate the development of

the protocol, the team can use the K/DOQI guidelines as the standard of care on which to base their protocol. They also should have a strong understanding of managing anemia with IV iron and EPO therapy, interpreting iron measures, and assessing infection and inflammation. In addition, the team can utilize their EPO and iron vendors as a resource for information and educational programs on erythropoiesis and the need for iron.

Strategy #5

An effective protocol should accomplish the following:

- Stabilize Hgb values and improve patient outcomes (in a majority of patients).
- Optimize EPO and IV iron dosing.
- Decrease wastage and potential medication errors.
- Remind anemia managers and clinicians that patient-specific interventions are still necessary, even with a protocol.
- Simplify the entire iron and anemia management process.

Conclusion

One of the main obstacles to successfully managing anemia is iron deficiency, which is common in patients with CKD and ESRD. Therefore, the anemia management team at the Kidney Institute of Wisconsin - Northeast Unit developed and implemented an IV iron maintenance protocol using a CQI program. By dividing the treatment process into a simple protocol for nurses and a general assessment guideline for the anemia manager, the facility was better able to utilize staff time and improve outcomes with both regulated and patient-specific care. As a result of the new protocol and the conversion from iron sucrose to sodium ferric gluconate, the facility experienced a decrease in the percentage of patients with a serum ferritin >800 ng/mL and an increase in the percentage of patients with an Hgb >11 g/dL. In addition, it was

determined that the new protocol was easier to follow and it simplified the entire treatment process.

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Using CQI Strategies to Improve and Simplify IV Iron and Anemia Management: A Dialysis Facility's Experience

Deborah Bowe, RN, CNN, and Debra Ammel, MS, RD, CD

Posttest – 1.8 Contact Hours

Posttest Questions

(See posttest instructions on the answer form, on page 545.)

- As patients reach target Hgb, they usually experience**
 - improved quality of life.
 - reticuloendothelial blockade.
 - left ventricular hypertrophy.
 - EPO hyporesponse.
- Key components of a continuous quality improvement program include(s) identification of the following:**
 - management team only.
 - management team and current processes only.
 - management team, current processes, and opportunities for improvement only.
 - management team, current processes, opportunities for improvement, and intervention plan.
- An analysis by Gilmartin (*Nephrology Nursing Journal*, 2004) showed what dose of ferric gluconate weekly or every other week resulted in steady iron levels, EPO doses, and Hgb levels?**
 - 25.5 mg
 - 50 mg
 - 62.5 mg
 - 100 mg
- An analysis by Schmidt et al. (*Dialysis & Transplantation*, 2005) showed that the average hemodialysis patient receives between what dose of IV iron weekly, regardless of product or protocol?**
 - 60 and 64 mg
 - 70 and 74 mg
 - 80 and 84 mg
 - 90 and 94 mg
- Patients with CKD, particularly those on hemodialysis, often lack adequate iron stores due to blood loss from**
 - GI bleeding only.
 - GI bleeding and dialysis-related procedures only.
 - GI bleeding, dialysis-related procedures, and frequent laboratory tests only.
 - GI bleeding, dialysis-related procedures, frequent laboratory tests, and infection.
- After implementing a new protocol using sodium ferric gluconate, the Kidney Institute of Wisconsin – Northeast Unit identified the following outcome:**
 - increase in the number of patients with ferritin >800 ng/mL.
 - decrease in the percentage of patients with Hgb >11 g/dL
 - decrease in the average serum ferritin level.
 - increase in the average EPO dose.
- Prior to the new protocol, the Kidney Institute of Wisconsin – Northeast Unit cited iron deficiency as the most frequent cause of low Hgb levels and lack of EPO response. What is the leading cause now?**
 - Infection only
 - Infection and surgery only
 - Infection, surgery, and GI bleed only
 - Infection, surgery, GI bleed, and inadequate dose of EPO
- Mr. Harold has the following labs: TSAT 19%, ferritin 560 ng/mL, and Hgb 10.8 g/dl. According to the protocol, you should do what first?**
 - Evaluate current EPO dose for adequacy.
 - Draw a CRP.
 - Assess patient for infection.
 - Administer ferric gluconate 125 mg IV x 8.
- Mrs. Johnson has the following labs: ferritin of 1130 ng/mL, TSAT of 18%, and Hgb 10.7 g/dL. You should evaluate Mrs. Johnson for which of the following?**
 - Infection only
 - Infection and inflammation only
 - Infection, inflammation, and current IV iron dose only
 - Infection, inflammation, current IV iron dose, and PTH level
- Mr. Carolton's Hgb is 10.3 g/dL and has been below 11 g/dL for the past 3 months. Mr. Carolton has been receiving 62.5 mg of ferric gluconate weekly. TSAT is 25% and ferritin is 332 ng/ml. He weighs 100 kg and is receiving 30,000 units of EPO 3 times per week at hemodialysis. What test might you perform to further evaluate Mr. Carolton's anemia?**
 - Stools for occult blood
 - Stools for occult blood and CRP
 - Stools for occult blood, CRP, and PTH level
 - Stools for occult blood, CRP, PTH level, and potassium level



ANNJ512

ANSWER FORM

Using CQI Strategies to Improve and Simplify IV Iron and Anemia Management: A Dialysis Facility's Experience

Deborah Bowe, RN, CNN, and Debra Ammel, MS, RN, CD

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.
- Posttests must be postmarked by October 20, 2007. If you receive a passing score of 70% or better, a certificate for 1.8 contact hours will be awarded by ANNA.
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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 | | Strongly agree |
|---|-------------------|---|----------------|
| 1. The objectives were related to the goal. | 1 | 2 | 3 4 5 |
| 2. Objectives were met | | | |
| a. Discuss the importance of iron in treatment of anemia. | 1 | 2 | 3 4 5 |
| b. Examine how a dialysis facility used a CQI program to develop and implement an IV iron protocol. | 1 | 2 | 3 4 5 |
| c. Identify practical strategies to help initiate an iron protocol and improve outcomes. | 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. I am more confident of my abilities since completing this material. | 1 | 2 | 3 4 5 |
| 6. The material was (check one) ___ new, ___ review for me. | | | |
| 7. Time required to complete reading assignment: _____ minutes. | | | |

GOAL

To describe how to improve outcomes with the development and implementation of a simplified IV iron and anemia management protocol.

I verify that I have completed this activity:

(Signature)

Comments _____

Suggested topics for future articles? _____