

## The KDOQI™ Clinical Practice Guidelines And Clinical Practice Recommendations for Treating Anemia in Patients With Chronic Kidney Disease: Implications for Nurses

Patricia McCarley

The National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI™) Clinical Practice Guidelines and Clinical Practice Recommendations have had a significantly positive impact on the quality of care for patients on dialysis. The KDOQI™ initiative is guided by volunteer nurses, physicians, and allied health care providers who have developed guidelines and recommendations addressing the diagnosis, monitoring, and clinical management of all stages of chronic kidney disease (CKD). To date, the KDOQI™ has developed 11 guidelines on a wide variety of clinical topics (see Table 1) and continues to update these guidelines periodically as new evidence becomes available (NKF, 2006).

Recently, the KDOQI™ published an update of its guidelines and recommendations for treating anemia across the entire CKD spectrum. The newly revised anemia guidelines distinguish between evidence-based *clinical practice guidelines* and expert-opinion-based *clinical practice recommendations*.

For topics on which the quality of the evidence was strong or moderately strong, the Work Group developed evidence-based clinical practice guidelines. These guidelines

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*The National Kidney Foundation Kidney Disease Outcomes Quality Initiative recently published revised clinical practice guidelines and recommendations for the treatment of anemia. This article provides an overview of the new guidelines and recommendations, with a focus on the hemoglobin treatment range, iron status, use of erythropoiesis-stimulating agents, and adjuvant therapies.*

### Goal

Discuss how the KDOQI™ 2006 anemia guidelines differ from previous guidelines, and the implications for nursing practice.

### Objectives

1. Explain three ways in which the new anemia guidelines differ from previous guidelines.
2. Describe the rationale for the revised Hb treatment range.
3. List three action items that nurses may have to undertake to operationalize the new anemia guidelines.

were derived from reproducible data from prospective, randomized, controlled clinical trials that included safety information and were conducted in patients with CKD. Data from observational, nonrandomized, longitudinal, or uncontrolled trials were not deemed adequate for the clinical practice guideline designation (NKF, 2006). When adequate data from randomized, controlled trials were not available, the members of the Work Group used their clinical experience and less rigorous clinical data to develop expert-opinion-based clinical practice recommendations. The phrase “in the opinion of Work Group members”

precedes each clinical practice recommendation to distinguish it from an evidence-based guideline (NKF, 2006).

It should be noted that while the KDOQI™ clinical practice guidelines and recommendations provide information that can be invaluable in helping nurses and other clinicians make decisions on patient care, they are not intended to define an exclusive course of management or to preclude individualization of a therapeutic approach to meet the needs of a specific patient (NKF, 2006).

This review centers on the primary changes in the clinical practice guidelines and recommendations for

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**Table 1**  
**NKF-KDOQI™ Clinical Practice Guidelines and Recommendations**

Anemia Bone Metabolism and Disease Cardiovascular Disease Vascular Access Hemodialysis Peritoneal Dialysis Nutrition Hypertension CKD Evaluation Dyslipidemia Diabetes (in development)
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adult patients on dialysis, with a focus on how these changes may affect nursing practice and patient management. The changes center on four primary areas: (a) hemoglobin (Hb) treatment range, (b) target iron status, (c) erythropoiesis-stimulating agents (ESAs), and (d) adjuvant therapies.

### Hemoglobin Treatment Range

The previous KDOQI™ anemia guidelines recommended a target Hb range of 11.0 to 12.0 g/dL (see Table 2). The new KDOQI™ Clinical Practice Guideline recommends a Hb of at least 11.0 g/dL for all patients who have CKD and anemia, regardless of whether they are receiving dialysis therapy. The evidence supporting a Hb of 11.0 g/dL or greater was compiled from 22 controlled, intent-to-treat trials that compared patients treated with erythropoiesis stimulating agents (ESAs) versus placebos or patients treated with ESAs randomized to achieve a lower versus a higher Hb (specific Hb targets varied among studies). Ten of these studies were in patients on hemodialysis, one was in patients on peritoneal dialysis, two enrolled patients on both peritoneal dialysis and hemodialysis, and nine enrolled patients who had CKD but were not on dialysis. Evidence from observa-

**Table 2**  
**Key Differences Between the 2006 KDOQI™ Anemia Clinical Practice Guidelines and Recommendations and the Previous Guidelines**

Topic	KDOQI™ 2000	KDOQI™ 2006
<b>Hb Treatment Range</b>	11.0 to 12.0 g/dL	<ul style="list-style-type: none"> <li>At or above 11.0 g/dL</li> <li>Caution when intentionally maintaining Hb &gt; 13.0 g/dL</li> </ul>
<b>TSAT</b>	20% to 50%	<ul style="list-style-type: none"> <li>Lower boundary of 20%</li> <li>Upper boundary not specified</li> </ul>
<b>Ferritin</b>	100 to 800 ng/mL	<ul style="list-style-type: none"> <li>Lower boundary of 100 ng/mL for peritoneal dialysis and 200 ng/mL for hemodialysis</li> <li>Ferritin greater than 500 ng/mL not routinely recommended</li> </ul>
<b>Adjuvants</b>	L-carnitine not recommended	<ul style="list-style-type: none"> <li>L-carnitine and vitamin C not routinely recommended</li> <li>Androgens not recommended</li> </ul>

tional trials was excluded from this analysis (NKF, 2006).

The Clinical Practice Guideline calling for a minimum Hb of 11.0 g/dL was based on data showing significant improvements in quality of life when the Hb was maintained above this threshold. The analysis found a consistently positive relationship between improvements in quality of life outcomes and higher Hb levels, with continuous and incremental improvements seen as Hb levels increased from 6.0 to 16.0 g/dL. In these studies, patients with higher Hb levels reported more vitality, less fatigue, improved physical symptoms, and less depression than did patients with lower Hb levels (NKF, 2006). The improvements in quality of life were more readily discernible in clinical trials that used testing instruments specific for CKD.

The clinical practice recommendation for the upper Hb level is 13.0 g/dL. In the opinion of the Work Group, there is insufficient evidence to recommend *routinely* maintaining

Hb levels at 13.0 g/dL or greater in patients treated with ESAs. Although the quality of life benefits observed in randomized, controlled studies extended well beyond the 13.0 g/dL level, Work Group members thought that efforts to gain incremental improvements in quality of life by maintaining Hb levels at 13.0 g/dL or greater are countered by an increased risk of adverse events, some of which may be life-threatening or disabling.

The Work Group also noted that clinicians should not be alarmed if Hb levels transiently exceed the 13.0 g/dL limit. When clinicians strive for a minimum Hb of 11.0 g/dL, natural variability will dictate that a sizable fraction of patients will have transient levels greater than 13 g/dL. A temporary spike above 13.0 g/dL is not seen as a safety concern, and judicious adjustments in the ESA dose seem sufficient to lower Hb below this threshold within 3 to 6 months. This upper threshold does not apply to the small group of patients who

maintain a Hb at or above 13.0 g/dL without ESA therapy (NKF, 2006).

The Clinical Practice Guideline recommending a minimum Hb level of 11.0 g/dL is identical to the previous KDOQI™ recommendation and should not require a significant change in anemia protocols. The Work Group thought that the minimum Hb level of 11.0 g/dL is a readily achievable goal for all patients on dialysis. More than 80% of prevalent patients on hemodialysis have Hb levels that exceed 11.0 g/dL, and among those whose Hb is below that threshold, more than 99.6% achieve a level of 11.0 g/dL or greater within 6 months when prescribed an appropriate dose of Epoetin alfa (NKF, 2006). Thus, the Work Group felt that the guideline could be readily implemented into clinical practice, with ongoing quality improvements directed at increasing the percentage of patients who achieve and maintain the Hb level above the 11 g/dL threshold.

However, the Clinical Practice Recommendation for an upper Hb limit of 13.0 g/dL may require dialysis facilities to modify their anemia management protocols. This recommendation represents a significant change from the narrower target range of 11.0 to 12.0 g/dL outlined in the previous guideline and should allow more flexibility in managing patients who exhibit natural variability in Hb levels. This recommendation also parallels the new Centers for Medicare and Medicaid Services (CMS) Erythropoietin Claims Monitoring Policy, which mandates a 25% reduction in the monthly dose of Epoetin alfa when Hb levels exceed 13.0 g/dL during the preceding month (Messana, 2006).

### **Iron Measurement and Therapy**

The revised report includes several changes in the target ranges for iron therapy and provides Clinical Practice Recommendations for using the results from iron indices as treatment targets to guide the safe and effective use of iron agents. Earlier versions of the KDOQI™ guidelines

recommended a ferritin level of 100 to 800 ng/mL for all patients on dialysis. The new recommendations differentiate between dialysis populations and recommend that ferritin levels be maintained above 200 ng/mL for patients on hemodialysis and above 100 ng/mL for patients on peritoneal dialysis as well as for patients with CKD. The clinical practice recommendation for ferritin concerning treatment targets reflects a conservative estimate of efficacy and a cautious approach to patient safety.

In the opinion of the Work Group, there is insufficient evidence to recommend the *routine* administration of intravenous (IV) iron if the serum ferritin is above 500 ng/mL. This recommendation is based on the following findings: (a) there are no randomized, controlled trials that have compared the safety and efficacy of ferritin levels above 500 ng/mL with lower levels, (b) only a handful of studies have examined the efficacy of IV iron when administered to patients whose ferritin is above 500 ng/mL, (c) no interventional trials have proven the safety of ferritin targets above 500 ng/mL, and (d) evidence suggests that tissue iron stores are normal or above normal in patients whose ferritin is above 500 ng/mL. The Work Group also observed that a therapeutic response to 1,000 mg of IV iron is unlikely in a patient whose ferritin is in excess of 500 ng/mL (NKF, 2006).

While efficacy and safety concerns resulted in the Work Group's recommendation that administration of IV iron in patients whose ferritin is above 500 ng/ml not be routine, the Work Group acknowledged that ferritin levels often temporarily spike above 500 ng/ml. In addition, although administering IV iron when the ferritin level is above 500 ng/mL is not routinely recommended, the anemia guideline does not preclude doing so if it is warranted on the basis of ESA responsiveness, the Hb level, and the patient's clinical status (NKF, 2006).

The anemia guidelines provide a clinical practice recommendation for

a target transferrin saturation (TSAT) of 20% or greater, which is identical to the previous guideline. However, unlike the previous anemia guidelines, which set an upper TSAT limit of 50%, the new anemia guidelines do not define an upper boundary. The new guideline notes that patients with a TSAT at or above 20% may still show absent bone marrow iron or respond to an IV iron challenge (NKF, 2006).

The new anemia guidelines also include a clinical practice recommendation for assessing the content of hemoglobin in reticulocytes (CHr), which has been used in several clinical studies as an alternative to the TSAT to assess iron availability. On the basis of evidence from two randomized, controlled trials comparing the use of CHr and TSAT, the anemia guidelines recommend that the CHr level be greater than 29 pg/mL. However, the Work Group also noted that functional iron studies on the clinical utility of CHr provide varying and inconsistent results and that CHr assessments may also vary depending on the laboratory instrument that is used (the KDOQI™ recommendation is based on the Advia 120 instrument) (NKF, 2006).

Finally, the new anemia guidelines provide a Clinical Practice Guideline with a strong recommendation that iron be administered by the IV route to patients on hemodialysis. This Clinical Practice Guideline was based on results from four randomized controlled trials that showed that oral iron was not demonstrated to be more effective than either no treatment or placebo and IV iron is superior to oral iron. In contrast, the Work Group issued an opinion-based Clinical Practice Recommendation that iron can be administered by either the IV or oral routes in patients on peritoneal dialysis (NKF, 2006).

How will the new Clinical Practice Recommendations on iron affect nursing practice? Data indicate that ferritin levels have been increasing progressively over the past 10 years. The most recent report from

the End Stage Renal Disease Clinical Performance Measures Project revealed that the national TSAT average among patients on dialysis was 29.3%, with a range of 27.1% to 32.0% among Renal Networks. In the same evaluation, the mean ferritin level in the country was 596 ng/mL (ranging from 517 to 660 ng/mL among Networks) (CMS, 2004).

The revised recommendation for not targeting a ferritin level in excess of 500 ng/mL will represent a change for most dialysis centers and may require a modification in anemia management protocols. The overall goal of iron replenishment should be neutral iron balance – providing enough iron to support ESA-stimulated erythropoiesis without experiencing ongoing increases in ferritin. In the analysis conducted by KDOQI™, the amount of IV iron typically required to maintain neutral iron balance in patients on hemodialysis ranged from 22 to 65 mg/week, with higher doses potentially leading to progressive increases in ferritin (NKF, 2006). However, it is critical that nurses evaluate each individual patient's response to IV iron. Appropriate iron supplementation should be determined on the basis of ESA responsiveness, the Hb level, and the patient's clinical status.

### Administration of ESAs

Although either IV or subcutaneous (SC) administration of ESAs is feasible, the Work Group indicated that convenience favors IV administration in patients on hemodialysis and SC administration in patients on peritoneal dialysis (NKF, 2006). The Work Group also observed that while the risk of pure red cell aplasia associated with SC administration of ESAs is small, it recently prompted the U.S. Food and Drug Administration to recommend using the IV route for ESAs.

The new KDOQI™ Clinical Practice Recommendation states that ESA doses should typically be decreased and not held when a downward adjustment in Hb is

required. The Work Group observed that withholding ESA doses, particularly for long periods of time, may lead to a fall in Hb and an increase in Hb variability. The Work Group clarified that doses should not be held routinely for factors such as a Hb above the target, hospitalization, hypertension, or vascular access occlusion since there is no evidence that withholding doses improves patient outcomes (NKF, 2006).

The Work Group recommends replacing a missed ESA dose as soon as possible. For example, if a patient who is receiving 10,000 Units/dose of Epoetin alfa misses a dose, the next dose should be 20,000 Units – thereby making up the missed dose. This recommendation is based on the Work Group's concern that missed doses may lead to a decrease in Hb that is not immediately apparent. Since ESAs work by protecting red blood progenitors from apoptosis (preprogrammed cell death), any missed or withheld dose may lead to a decrease in Hb and/or an increase in Hb variability. It is therefore prudent to ensure that patients receive the total prescribed dose (NKF, 2006).

How will the new ESA administration recommendations affect nursing practice? Most dialysis facilities in the United States currently administer ESAs by the IV route to patients on hemodialysis and by the SC route to patients on peritoneal dialysis. The confirmation of this trend by the new KDOQI™ recommendation should therefore not have a significant impact on clinical practice. The recommendations for not routinely withholding ESA doses and replacing missed doses may represent a significant change for many dialysis facilities and may require a modification in the anemia management protocol.

### Adjuvants to ESA Therapy

The Work Group examined a wide range of clinical data to determine whether pharmacological or nonpharmacological adjuvants can enhance the response to ESA therapy

in patients who are iron replete. This evaluation focused on patients on hemodialysis, since sufficient study data are not available to address the use of adjuvants to ESA treatment in patients on peritoneal dialysis (NKF, 2006). Specific recommendations were provided for L-carnitine, vitamin C, and androgens.

While L-carnitine has been used as an adjuvant to ESA therapy, the role of carnitine deficiency in the pathogenesis of anemia remains unclear, and no mechanism by which carnitine deficiency could cause anemia or ESA hyporesponse has been conclusively proven. Therefore, in the opinion of the Work Group, there is not enough evidence to recommend using L-carnitine in the management of anemia (NKF, 2006).

The same Clinical Practice Recommendation was made for vitamin C (ascorbate). Although some studies have found that vitamin C may increase the release of macrophage-bound iron in the reticuloendothelial system, randomized, controlled studies have not shown IV or oral vitamin C to have a consistent benefit in anemia management. Further, the long-term safety of IV vitamin C is unclear, and the potential for causing oxalosis remains a concern (NKF, 2006).

The Work Group issued a Clinical Practice Guideline with a strong recommendation that androgens not be used as an adjuvant to ESA therapy. Before Epoetin alfa was available, androgens were widely used to treat anemia in patients on dialysis. However, these agents were accompanied by a range of potential adverse events, including liver dysfunction, priapism, virilization, acne, injection-site pain, and an increased risk for hepatocellular carcinoma and peliosis hepatis. A review of randomized, controlled studies found that the enhanced erythropoiesis that may be associated with the administration of androgens did not outweigh the potentially significant adverse events associated with them (NKF, 2006).

The Work Group also examined a wide range of other pharmacological or nonpharmacological therapies as potential adjuvants to ESA therapy, including statins, pentoxifylline, vitamin B<sub>12</sub>, folate, vitamin E, high-dose dialysis, ultrapure dialysate, hemodiafiltration, daily and nocturnal hemodialysis, and peritoneal dialysis. However, there was not enough evidence to support the efficacy of these therapies (NKF, 2006).

## Conclusions

The updated KDOQI™ Clinical Practice Guidelines and Clinical Practice Recommendations for managing the anemia of CKD provide new insights gleaned from the most comprehensive review of the clinical literature to date. These revised Clinical Practice Guidelines and Clinical Practice Recommendations will provide improved flexibility in managing anemia and should encourage incremental improvement in Hb outcomes among patients on dialysis.

The rigorous nature of the process used to review the available clinical literature and formulate the updated anemia guidelines provided several new insights into the management of anemia. However, it should be noted that only enough randomized, controlled trials were available to allow the development of 3 Clinical Practice Guidelines – the other 32 Clinical Practice Recommendations found in the new KDOQI™ anemia update are based on less rigorous clinical literature and the expert opinions of the Work Group. Thus, while tremendous progress in anemia management has been achieved, there are still significant opportunities to conduct rigorous clinical research that could help clarify how to further enhance anemia-related outcomes. As the health care professionals responsible for the day-to-day management of anemia in patients on dialysis, nurses should play a key role in these future clinical trials.

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# The KDOQI™ Clinical Practice Guidelines and Clinical Practice Recommendations for Treating Anemia in Patients With Chronic Kidney Disease: Implications for Nurses

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Posttest – 1.4 RN CE Contact Hours & 20 Minutes of Pharmacology CE Hours

## Posttest Questions

(See posttest instructions on the answer form, on page 429.)

- 1. A Clinical Practice Guideline is based on**
  - A. data from retrospective, randomized controlled clinical trials.
  - B. data from prospective, randomized controlled clinical trials.
  - C. data from current, on-going controlled clinical trials.
  - D. data from less rigorous clinical trials and the European guidelines.
- 2. A Clinical Practice Recommendation is based on**
  - A. data from retrospective, randomized controlled clinical trials.
  - B. data from prospective, randomized controlled clinical trials.
  - C. data from less rigorous clinical trials and the European guidelines.
  - D. data from less rigorous clinical trials and expert opinion.
- 3. The new Clinical Practice Guideline recommends a minimum Hb level of at least**
  - A. 11.0 g/dL.
  - B. 11.5 g/dL.
  - C. 12.0 g/dL.
  - D. 12.5 g/dL.
- 4. The recommendation for the minimum Hb level was based on data from rigorous trials showing that patients maintained above this threshold had significant improvements in**
  - A. mortality.
  - B. hospitalization.
  - C. quality of life.
  - D. cardiovascular function.
- 5. The clinical practice recommendation for the upper Hb level is**
  - A. 11.5 g/dL.
  - B. 12.0 g/dL.
  - C. 12.5 g/dL.
  - D. 13.0 g/dL.
- 6. For patients on hemodialysis, the clinical practice recommendation sets a lower limit for ferritin of**
  - A. 100 ng/mL.
  - B. 150 ng/mL.
  - C. 200 ng/mL.
  - D. 250 ng/mL.
- 7. For patients on dialysis, the clinical practice recommendation suggests evaluating the patient and his response to ESA when the ferritin is**
  - A. 300 ng/mL.
  - B. 400 ng/mL.
  - C. 500 ng/mL.
  - D. 600 ng/mL.
- 8. One of your patients who receives 15,000 Units/dose of Epoetin alfa misses a dialysis session. The clinical practice recommendation for the next dose is**
  - A. 15,000 Units.
  - B. 20,000 Units.
  - C. 25,000 Units.
  - D. 30,000 Units.
- 9. On the basis of potential adverse effects such as liver dysfunction and virilization, the clinical practice guideline provides a strong recommendation not to use \_\_\_\_\_ as an adjuvant to ESA therapy.**
  - A. androgens
  - B. vitamin C
  - C. L-carnitine
  - D. Pentoxifylline
- 10. The fact that future research is still required on the topic of anemia management is supported by the fact that appropriate randomized controlled trials were available to support the development of only \_\_\_\_\_ Clinical Practice Guidelines.**
  - A. 1
  - B. 3
  - C. 5
  - D. 7

This activity offers both nursing (CE) contact hours and Pharmacology (P) contact hours for qualified applicants. See next page for details.

ANNJ616

## ANSWER/EVALUATION FORM

### The KDOQI™ Clinical Practice Guidelines and Clinical Practice Recommendations for Treating Anemia in Patients With Chronic Kidney Disease: Implications for Nurses

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**Posttest Instructions**

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- |            |            |            |            |             |
|------------|------------|------------|------------|-------------|
| 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	<b>GOAL</b> Discuss how the KDOQI™ 2006 anemia guidelines differ from previous guidelines, and the implications for nursing practice.
1. The objectives were related to the goal.	1	2	I verify that I have completed this activity: _____ (Signature) Comments _____ _____ Suggested topics for future articles? _____ _____
2. Objectives were met	1	2	
a. Explain three ways in which the new anemia guidelines differ from previous guidelines.	1	2	
b. Describe the rationale for the revised Hb treatment range.	1	2	
c. List three action items that nurses may have to undertake to operationalize the new anemia guidelines.	1	2	
3. The content was current and relevant.	1	2	
4. This was an effective method to learn this content.	1	2	
5. Time required to complete reading assignment: _____ minutes.			