Commentary in Response to Controversies in Nephrology

Development of Clinical Practice Guidelines: Are We Defining the Issues Too Narrowly?

Eleanor D. Lederer
Louisville VA Medical Center and University of Louisville Kidney Disease Program, Louisville, Kentucky


My thanks to the editors of CJASN for publishing the series of commentaries on the role of industry in the development of the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines and potential conflicts of interest. I raise two issues in response.

Conflict of interest goes well beyond financial considerations between individual investigators and industry backers. Academic medical centers, editorial offices, and the media have turned the conflict-of-interest spotlight almost exclusively on the issue of potential personal financial gain from industries with which a specific researcher has financial ties. This single-minded view of conflict of interest ignores another important motivation for performance of research: Esteem and recognition. Investigators pursue self-affirmation through acknowledgment that their work is credible and important. Therefore, if I have studied phosphate metabolism for my entire life (which I have), then I will be considered an expert in the field, but I am also likely to consider phosphate to have a major role in human physiology (which I do). Is that a conflict of interest if I am asked to define clinical practice guidelines for chronic kidney disease? Am I perhaps likely to place a greater emphasis on control of phosphate and give more weight to studies in which control of phosphate has a more salutary effect on morbidity/mortality than control of BP or serum lipids? Another more subtle conflict of interest is “fundability” of a specific topic. Investigators can study a question only when there is money to fund the study, whether that money comes from industry, the National Institutes of Health, or other funding agencies. Are there clinical issues that we should be addressing in the development of clinical practice guidelines that are not being studied because of conflicts of interest in peer review?

The second issue I raise is perhaps more treacherous in its implications. Undoubtedly, the individuals who were involved in developing the KDOQI guidelines worked hard not only to develop the guidelines but also to point out the limitations of the evidence involved. However, it is not clear to me in my practice that these limitations are incorporated into either the dissemination of the guidelines or the assessment of my nephrology practice. Instead, the monthly dialysis note on my patients dutifully records whether I have achieved a guideline goal for each and every patient, and I know that somewhere in cyberspace, each guideline success and failure is being recorded. At a time when performance-based reimbursement is being seriously considered, how will these data be used in consideration of my reimbursement? Furthermore, will the widespread implementation of these guidelines stifle further research in the area as a result of the misperception among health care providers and granting agencies that because a guideline has been developed, the question has been answered?

Neither of these issues presents difficulties that are impossible to address. I raise them to heighten awareness of considerations that I do not believe have been adequately addressed in the medical or lay literature.

Disclosures
None.

Clearly, anemia guidelines continue to be somewhat controversial, including determining the exact target for hemoglobin with erythropoietin therapy as well as the role of parenteral iron in patient management. In this month’s issue of JASN, a study by Coyne et al. (pages 975–984) randomizing patients to no iron versus IV iron gives some insights into the efficacy of parenteral iron in patients receiving adequate erythropoietin dosage. Clearly, abnormalities in iron metabolism must be factored into a multidisciplinary approach to patient management.