

Patient Care Guidelines: Problems and Solutions

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This month's *CJASN Controversies* section presents two discussions of interactions between industry and the KDOQI patient care guidelines for the treatment of anemia in chronic kidney disease and ESRD. In subsequent issues we will present invited commentaries from other authorities in this area and invite our general readership to express their opinions.

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A progressively expanding scientific literature continuously reshapes and modifies complicated issues in patient management. As new studies appear, old therapies often are invalidated while others acquire broader scientific endorsement. This changing therapeutic landscape challenges the ability of many physicians to remain current and, thereby, sustain delivery of the highest quality patient care.

Assimilating this new information while clinical and administrative workloads continuously increase presents a difficult challenge to many clinicians. As a result of these pressures, an alarming number of physicians utilize representatives of the pharmaceutical and medical device industries to access newly published information as a part of their detailing activities.

To address this "information explosion" in renal disease, the American Society of Nephrology (ASN) offers a wide array of learning instruments that minimize the educational burden and assures nephrologists that the material has been reviewed critically to eliminate commercial bias. Patient Care Guidelines (PCG) offer one way of keeping medical practice current and scientifically based. When properly done, such PCGs formulate an evidenced-based approach to patient care that is derived from carefully developed and executed clinical studies. Complicated case management benefits from the scientific stability that is provided by such an approach. However, this is an area where medical and mercantile interests may collide; therefore, extreme care must be taken to develop these guidelines rigorously without the taint or perception of commercial bias.

Outstanding authorities devoid of conflicting entanglements with industry can meticulously review, critique, and summarize the relevant literature and base their guidelines on solid scientific information. When the evidence is "soft," recommendations may be offered as "opinion," if clearly stated. To avoid the intermixing and confusion of evidence-based with opinion-based guidelines, many have argued persuasively that they should be published separately.

We believe that most published PCGs are credible and help-

ful. Their value derives from assiduously insulating the committee members from the potential influences of industry and providing the necessary time to cull the best studies from the literature and to debate the findings. Logic demands that patient care should benefit from this process; however, testing whether these guidelines indeed ultimately influence patient care in a positive way remains a fertile area for further clinical investigation.

In developing these complex guidelines, it is critical that any situation that blurs the line that separates our patients' best medical interests from the oftentimes conflicting business demands of industry be avoided. Real or perceived influences of industry will lessen the credibility of the process and taint its conclusions. Needless to say, representatives from companies that support the PCG developmental process should not have direct access to the committee's evolving discussions or the opportunity to influence directly or indirectly the individual committee members.

Two areas where the collision of business and medical interests are most obvious are in the provision of financial support for the PCG development process and when committee members receive from industry substantial fees for consultancies, speaking engagements, or separate support for research grants. Both present formidable but, we believe, resolvable problems.

A properly done PCG process is arduous, time-consuming, and expensive. Federal and professional society support for the program, as is done, for example, with the guidelines that are developed by the Joint National Commission for Hypertension, clearly is the best solution. Companies that are committed to advancing quality care may have the very best intentions when they contribute to the costs of the guideline process; however, this creates by definition a conflict of interest. The conflict may be resolved if contributions are placed in a common pool for the development of all guidelines, not just those that are related to the contributor's commercial interests. Companies should agree to adhere to strict requirements that insulate the committees from any outside influence. Violations of this agreement should carry, at the very least, the penalty of public exposure.

We recognize that the pool of experts who would best serve the PCG process often includes those who receive some form of support from companies that have a vested interest in one or more guideline development committees. Excluding such au-

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thorities would likely compromise the expertise of the committee. Certainly, every attempt should be made to select highly qualified members who have minimal conflict, and, whenever possible, the committee chair or co-chair should be free of ties to contributing companies. Complete and public disclosure of conflicts should be published with the guidelines and be highly visible. A very careful policy that outlines when a conflicted committee member must recuse him- or herself from voting also is critically important.

We need to realize that these guidelines may be used by the legal profession and health insurers to justify prosecution or defense of malpractice cases or as inviolable practice standards. Physician reimbursement may be based on achieving targets in the name of quality improvement. The potential for abuse, however, likely is overridden by the scientific and clinical merit of these guidelines and commonsense application to individual cases. We hope we have made clear that we do not wish to

“throw the baby out with the bathwater,” and underscore our contention that a well-done and transparent PCG process remains in the very best interests of both the profession and patient care.

Disclosures

Dr. Bennett is the recipient of research grants from Roche and Otsuka Pharmaceuticals and is a consultant for Novartis Oncology. Dr. Narins is the former Director of Postgraduate Education for the ASN and subsequently was a consultant to the ASN.

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