Follow-ups

David B. Nash, MD, MBA

In the hurly burly of everyday clinical practice and our responsibilities as P&T committee members, perhaps you missed two interesting follow-up articles that we could have taken from the pages of P&T itself. I would like to focus our readers’ attention on these issues and to reinforce some of the many take-home messages from the follow-ups.

You might remember a commentary in P&T (September 2003) highlighting the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). Although our assessment of ALLHAT came under intense public scrutiny, my coauthors and I stand by our unbiased reassessment of the findings.

Maybe you missed an important Letter to the Editor, published in JAMA, from the Institute for Clinical Evaluative Sciences in Toronto, Ontario, Canada. Peter Austin and colleagues studied the impact of the publication of the ALLHAT trial, which first appeared in JAMA on December 18, 2002. Let me quickly summarize the authors’ methods and the fascinating finding from their little research project.

The Toronto team studied claims for antihypertensive agents that were submitted to the Ontario Drug Benefit Program from January 1, 1992, through April 30, 2003. This period covered prescriptions dispensed to all 1.3 million residents of Ontario who were older than 65 years of age (nicely mirroring our own Medicare population). For each month of the time period in question, the team determined the number of prescriptions filled for patients who had not had a prescription for any hypertensive agent in the previous year to establish the number of incident users of these agents. They also examined the proportion of new prescriptions within each of the four classes of these agents: the thiazide-type diuretics, the calcium-channel blockers, the angiotensin-converting enzyme (ACE) inhibitors, and the beta blockers. What did they find?

Not surprisingly (to me), in the first four months following publication of ALLHAT, the relative market share of thiazide diuretics increased significantly, compared with the number predicted by the team’s special time series model. For each month in question, this figure was statistically significant (P < .001). In other words, during this period, the relative market share of the thiazide diuretics was statistically significant and that of the ACE-inhibitors and angiotensin-receptor blockers (ARBs) decreased.

We all know that the thiazide diuretics, which are inexpensive and available in generic format, are one of the cornerstones of first-line antihypertensive therapy. I find it fascinating to see that prescriptions for diuretics gained market share at the expense of ACE-inhibitors and ARBs, both of which are newer, more expensive agents. In light of this fact, what is the main message?

I believe that ALLHAT, the surrounding publicity, and our P&T article all contributed to a reassessment of practice behavior by clinicians. As Dr. Naylor pointed out in an accompanying JAMA editorial, we basically know very little about what really influences physicians’ prescribing behavior. Is it the detail force, the printed journal ads, the exposure to material on the Internet, research studies in major journals and the accompanying press, or an alchemy-like combination of all of the above?

The truth lies somewhere in this witch’s brew. For P&T committee members, I believe that this controversy reinforces my view that we, as leaders in our own institutions, can have an impact on prescribing behavior by providing physicians with solid feedback in a timely way based on the best possible evidence. If it happens to decrease costs, then our hand is strengthened even more.

The second follow-up article appeared in a more recent issue of the Wall Street Journal, just after the New Year. You might remember my P&T editorial on counterfeit drugs and their effects across the nation (January 2004). I am happy to report that a group of state regulators is preparing tough new guidelines to “oversee pharmaceutical wholesalers in a move designed to crack down on counterfeit and diverted medicines.”

The National Association of Boards of Pharmacy (NABP), in a plan that is still being finalized in the early part of 2004, wants to require background checks for people seeking to be licensed as wholesalers and calls for stricter documentation of the origins of drugs. It is hoped that these guidelines will effectively weed out the legitimate wholesale distributors from those who should not be in the business in the first place, according to knowledgeable persons inside the NABP.

Not unexpectedly, the Healthcare Distribution Management Association (HDMA), which represents distributors, says that it has not yet formulated a policy response to the state regulators’ guidelines. What we have here is a classic capitalist economy response to an important health-related policy decision. The players—the Food and Drug Administration, the NABP, and the HDMA—must work together to protect the drug distribution pipeline. As I wrote in my editorial of two months ago, the proposal emanating from this controversy would close a loophole that has long made it difficult to track counterfeiters. Wholesalers that are authorized distributors would have to maintain so-called paper pedigrees, or documents that trace the origins of medicines. It is significant
that all distributors, starting in 2007, must have electronic versions of this documentation. This advance should make it easier to track certain lot numbers and potentially foil widespread counterfeiting rings.

I am happy that P&T is on the cutting edge of these socially important, policy-relevant topics, such as influencing physicians’ prescribing behavior and limiting the impact of counterfeit drugs. I am committed to staying on top of these issues and plan to address them on a regular basis for our readership.

As usual, I am interested in your views. You can reach me at my e-mail address, david.nash@jefferson.edu.

REFERENCES