Policy & Practice

Seeing Plaque Is Believing

Patients shown images of their own coronary artery calcium (CAC) comply better with statin therapy, researchers at the Los Angeles Biomedical Research Institute at the Harbor–University of California at Los Angeles Medical Center say. In a study published in Atherosclerosis, Dr. Matthew J. Budoff and colleagues looked at adherence to statin therapy in 505 patients who were among 1,215 consecutive patients who underwent electron beam tomography at the center. Overall, 72% remained on treatment at follow-up, almost 4 years after the baseline scan. As CAC scores increased, so did adherence, according to Dr. Budoff of the medical center's Research and Education Institute. Only 44% of those with a CAC score of zero were adherent, compared with 90% of those with a score in the highest two quartiles. Adherence seemed to be influenced mainly by the scan; the presence or absence of heart disease risk factors did not make a difference, said the authors. A randomized trial is needed to confirm the results, since this study was observational and relied on self-reports of medication use, they said.

High Cholesterol, But Not Worried

An American Heart Association survey found that half of those with a cholesterol level of 200 or more who had other risk factors such as high blood pressure did not think they were at risk for cardiovascular disease. The poll of 756 adults aged 35-75 years who have been diagnosed with high or borderline high cholesterol, also found 15% believed they were at low risk of cardiovascular disease. Seventy-two percent saw their health care provider as a partner in managing their cholesterol. People who discussed their condition more frequently with their provider were more informed on issues such as their personal goals (83% vs. 65% for infrequent discussers) and the importance of following a treatment plan (94% vs. 80%). The AHA released the survey as part of the 2006 Cholesterol Low Down program sponsored by Pfizer Inc.

GAO Raps FDA Decision Making

The Food and Drug Administration lacks a clear and effective process for making decisions about postmarketing drug safety issues, according to a recent report from the Government Accountability Office. The GAO noted that "there has been high turnover of Office of Drug Safety directors in the past 10 years, with eight different directors of the office and its various predecessors." Communication also is an issue; insufficient communication between the Office of Drug Safety and the Office of New Drugs divisions has been an ongoing concern and has hindered the decision-making process, the report said. The GAO suggested that Congress consider expanding the FDA's authority to require drug makers to conduct additional postmarket studies when needed. The GAO also recommended establishing a mechanism for specifically tracking postmarketing safety issues, and clarifying the Office of Drug Safety's role in the agency's advisory committee meetings. The FDA called the report "well done" and said that the GAO's conclusions were "reasonable and consistent with actions" already underway or planned.

Stem Cell Committee Named

The Institute of Medicine and the National Research Council, two divisions of the National Academies, have appointed a committee to "monitor and revise" voluntary guidelines on the conduct of human embryonic stem cell research. The committee will provide updates to the voluntary guidelines issued last year by the National Academies; it is currently seeking comments on the guidelines. The 14-member committee will be cochaired by R. Alta Charo, professor of law and bioethics at the University of Wisconsin, Madison, and Richard O. Hynes, Ph.D., investigator at the Howard Hughes Medical Institute and professor of cancer research at the Massachusetts Institute of Technology, Cambridge.

PBMs Say Generics Thwarted

At least 14 brand-name drugs are due to go off patent in the next 5 years, representing $23 billion in potential savings to Medicare Part D, but pharmaceutical manufacturers are doing all they can to block generic competition, according to the Pharmaceutical Care Management Association in a new report. This year alone, $1.5 billion could be saved on four drugs due to lose exclusivity: Zoloft (sertraline), Zocor (simvastatin), Proscar (finasteride), and Pravachol (pravastatin), the PCMA said. The FDA just approved a generic pravastatin (see p. 2). The savings estimates assume that 90% of Medicare prescriptions would be switched to generics and that the generic would cost 60% less than the brand name. In 2007, seven popular products—Norvasc (amlodipine), Ambien (zolpidem), Zyrtec (cetirizine), Lotrel (amlodipine/benazepril), Coreg (carvedilol), Lamisil (terbinafine), and Tequin (gatifloxacin)—are due to lose patent protection, which could lead to $700 million in savings that year, PCMA noted.

—Alicia Ault