Medication Samples Create Ethical Rift Among MDs

BY PATRICE WENDLING
Chicago Bureau

TUCSON, ARIZ. — Physicians are divided over whether it is ethical to use free sample medications in their practices, Nancy Sohler, Ph.D., and Dr. Diane McKee reported at the annual meeting of the North American Primary Care Research Group.

Accepting samples was viewed either as being ethically questionable or as a useful way of helping provide health care to low-income patients, according to findings from a study of 24 family medicine and general internal medicine physicians, nurses, and administrators in practices affiliated with a large urban medical center serving low- and middle-income patients in New York.

Interactions with pharmaceutical representatives were viewed as a direct conflict of interest, an influence that could be controlled, or a source of useful information. Of the total, 10 respondents felt that they could control the influence of drug firm representatives by keeping them away from residents, by setting limits on what gifts or favors could be accepted, or by always being mindful that representatives are selling a product, Dr. Sohler said in an interview.

For the respondents who drew a hard ethical line, "it wasn't that they thought giving out samples [to patients] was unethical, but that it wasn't good practice," she said.

Those who accepted samples said inadequacies in the health care system forced them to rely on gifts to care for their most needy patients.

All the respondents evaluated marketing practices from the perspective of protecting and serving their patients, said Dr. Sohler, professor of community health and social medicine, City University of New York, New York. No one was concerned that physicians were ignoring clinical symptoms to prescribe the "right drugs."

The study included in-depth, qualitative interviews and was prompted by an administrative decision at the medical center to ban samples and pharmaceutical representatives from the community practices. That decision left many providers uncertain about how to care for patients without adequate health care coverage. Others suggested that the policy was changed because the administration didn't want physicians taking the time to talk to sales representatives, didn't trust that staff would avoid entering into agreements with pharmaceutical firms, and did want a single policy, because teaching sites had a "no-rep" policy and other sites didn't need samples.

She said further study would be needed to determine whether samples help poor patients more than they harm them, and whether representatives influence prescribing practices in mostly helpful or harmful ways. "The empirical, quantitative evidence isn't good on whether free medications help or harm our patients," she said. ■

Yearly ED Visits Resulting From Adverse Drug Events Estimated at Over 700,000

BY MARY ANN MOON
Contributing Writer

More than 700,000 cases of adverse drug events are treated each year in emergency departments, according to estimates based on a nationally representative sampling of U.S. hospitals.

Of these, an estimated 117,000, or 1 in 6, are so severe that they require hospitalization, transfer to another health facility, or an ED admission for observation, according to the study, which was published in the Oct. 18 issue of the Journal of the American Medical Association.

People aged 65 years and older accounted for one-quarter of these adverse drug events and for more than half of those that required hospitalization, making the magnitude of the problem in this age group equivalent to that for injuries from motor vehicle accidents. People in this age group were more than twice as likely to need ED treatment and nearly seven times as likely to need hospitalization as younger people.

These findings, the first to be reported from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project, establish that adverse drug events are an important cause of morbidity, said Dr. Daniel S. Budnitz of the Centers for Disease Control and Prevention, Atlanta, and his associates.

The NEISS-CADES project assessed all incident ED visits explicitly attributed to the use of a drug at 63 hospitals that comprised a probability sample representative of all U.S. hospitals. The drugs included prescription and over-the-counter medications, vaccines, dietary supplements, and herbal products, but not illegal substances.

The adverse events included allergic reactions, undesirable pharmacologic or idiosyncratic effects that occur at recommended doses, toxic effects that stem from unintentional excess dosing or impaired excretion, and secondary effects such as falling because of drug-induced dizziness, the investigators said (JAMA 2006;296:1858-66).

Among the study's other findings:

- Most adverse drug events were due to unintentional overdoses. These include warfarin, insulin, and digoxin, which alone accounted for one-third of adverse events in older patients. Other such drugs were antidiabetic agents, anticonvulsants, theophylline, and lithium.
- The five most common drug classes implicated in adverse events were insulins, opioid-containing analgesics, anticoagulants, agents containing amoxicillin, and antihistamines/cold remedies.
- The most common drug reactions prompting the ED visits were dermatologic conditions, gastrointestinal problems, and neurologic conditions. Altered mental status, respiratory dysfunction, syncope, and cardiovascular effects also were common.
- About one-third of the adverse events were allergic reactions.
- Sixteen of the 18 drugs that caused most adverse events have been in use for over 20 years.

These results likely represent an underestimate of the total burden of adverse drug events, since they didn't include events treated in other settings, the researchers noted.

They also don't include adverse events unrecognized by ED physicians, according to Dr. Budnitz and his associates. ■

Medical School Gift Giving Bans: A Growing Trend?

BY TIMOTHY F. KIRN
Sacramento Bureau

SACRAMENTO — Another medical school has joined what could be a growing movement to ban faculty and residents from accepting any gifts whatsoever from drug company representatives.

The University of California, Davis, Health System decided in late November to forbid its medical staff to accept any gifts from drug salesmen, including drug samples, pens, mugs, and meals, however small they might be.

By taking this action, the school joins a cadre of institutions that includes Yale University, which implemented its policy in 2005, the University of Pennsylvania, which did so in July 2006, and Stanford University, which implemented its policy in October 2006. At UC Davis, the policy goes into effect in July 2007.

The new prohibition "picks off the low-lying fruit" in an attempt by the institution to create a greater distance between its clinical practice and the pharmaceutical industry, said Dr. Timothy E. Albertson, the university system's executive director of clinical care.

The efforts at UC Davis and the other academic medical centers were spurred in part by an article in the Journal of the American Medical Association (2006;295:429-33). The article noted that many authoritative bodies, including the Pharmaceutical Research and Manufacturers of America and government agencies, have made attempts to curtail practices that constitute a conflict of interest for physicians. But the article also said those actions have largely failed to change the current climate. Thus, the 11 authors of the paper urged academic medical centers to take the lead.

Academic medical centers need to adopt such policies because the medical profession looks to them for leadership, and because academic medical centers shape the ethics of the profession, the proposal said.

According to IMS Health, a pharmaceutical information and consulting company, drug companies spent $27 billion on product promotion in 2004, of which $16 billion was for free drug samples and $7.3 billion, including gifts and meals, went to sales representative contacts.

The pharmaceutical industry, which adopted strict guidelines on gift giving in 2002, says that limiting the practices and access of their sales representatives will deprive physicians of the best expertise on their medicines.

But gifts, however insignificant, establish an unspoken quid pro quo between physicians and pharmaceutical companies. If gifts did not serve this purpose, companies would not give them, the JAMA authors say. They note that the research bears this out.

According to a 2003 survey of more than 1,000 third-year medical students, an average third-year student receives one gift or attends one company-sponsored activity a week (JAMA 2005;294:1034-42). That is precisely the point of the no-gift policies proposed by the JAMA article, said one of its authors, Dr. Jerome P. Kassirer, former editor-in-chief of the New England Journal of Medicine.

"These meals and gifts give residents and trainees the idea that pharmaceutical largesse is all right and the way things work, but it taints the profession," Dr. Kassirer said in an interview. "They wouldn't pass out these gifts if it didn't matter.

"I think the academic medical centers needed a little nudge," he added, noting the impact the article appears to be having. "It's a beginning."

At the academic medical centers, free meals appear to be the biggest issue impeding acceptance of the policies among staff. The free meals allow physicians to attend midday meetings they otherwise would not have time to attend, and they are a big ticket item. At the UC Davis Cancer Center alone, it is estimated that companies spend about $70,000 on free lunches a year. The center will now pick up those costs, and other departments may have to do the same.

At the University of Pennsylvania Health System, the adoption of its policy caused some grumbling at first, along with the loss of some legitimate educational programs that were sponsored. For the most part, however, physicians and other staff members have adjusted, said Dr. Patrick J. Brennan, the chief medical officer of the university health system.

At UC Davis and some of the other institutions, efforts are being made to help patients who previously might have benefitted from receiving free drug samples or devices; these items have been very helpful, especially for lower-income patients, Dr. Albertson noted. The university is going to try to purchase some of the equipment that has been donated in the past, such as training inhalers for asthma patients and supplies for those with diabetes. "We're going to make every effort to buy them" for use by lower-income patients, he added. ■