Drug Samples Create Ethical Divide

BY PATRICE WENDLING
Chicago Bureau

TUCSON, ARIZ. — Physicians are divided over whether it is ethical to use free sample medications in their primary care practices, Dr. 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 that helped keep the practice up to date on new medications.

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. "They understood why others did it, but they worried about conflicts of interest with their interactions with the reps."

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

'People are drawing on their different values and perspectives to make a decision. We need hard evidence to make a policy.'

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," he said.

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 did not 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.

Dr. Sohler 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," Dr. Sohler said. "We realize that all marketing has an influence, but we don't know if it harms our patients.

"People are drawing on their different values and perspectives to make a decision. We need hard evidence to make a policy, but in the meantime, we should keep these perspectives in mind as the data come in." ■

Consensus Is Elusive on Financial Disclosure

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

Officials in charge of disclosing financial interests in research agree that disclosure is important, but are confused about how to do so effectively and appropriately, Kevin P. Weinfurt, Ph.D., and his colleagues reported.

Their survey of 42 such officials revealed widely varying opinions on when disclosure should be made, the financial limits that should trigger it, and how much information to share with prospective research subjects, said Dr. Weinfurt of the department of psychiatry at Duke University, Durham, N.C., and his coinvestigators.

"Part of their struggle relates to a lack of clarity regarding the ultimate goals of disclosure," the researchers wrote. "There is also a lack of systematic data regarding how potential research participants can and will use such information in their decision making" (J. Law Med. Ethics 2006; 34:581-91).

The study was based on detailed personal interviews with eight investigators, 23 review board chairs, and 14 conflict-of-interest committee chairs.

The survey was designed to elicit respondents' understandings of how disclosure is done at their institutions and their thoughts on the importance of disclosure, including its risks and benefits to the institution and research subjects.

More than half of those interviewed agreed that disclosure should occur under all circumstances; the rest said disclosure would depend on the degree of the financial relationship.

The most commonly expressed reason for disclosing a financial relationship was to facilitate better-informed decision making for potential subjects.

Other reasons included trust and transparency issues, reducing liability risk, and managing public perception of the institution.

About 80% of respondents said the disclosure should include the name of the funding source. But some said the name of the company or organization wasn't as important as a description—whether it was a nonprofit organization, pharmaceutical company, or government body, for instance.

They also differed on whether the amount of financial interest should be disclosed. Conflict-of-interest committee chairs were most likely to want to share this information (93%), while investigators were least likely (63%).

Those who expressed concern about disclosing the amount felt that level of detail could become cumbersome or confusing in the informed consent statement, and that research subjects might overestimate the impact that particular amounts might actually have on research outcomes.

There was no consensus on what amount should trigger disclosure—the lower limit ranged from $1 to $50,000.

There was general agreement that the nature of the relationship should be disclosed, but no agreement about whether the disclosure should explain the possible impact of those relationships.

Again, concern about overcomplicating the consent statement semed to be at the root of these issues.

Some respondents said the disclosure should include an explanation of how an unscrupulous investigator might alter the research results.

Most respondents dismissed the idea that disclosure could lower enrollment. There was little sympathy among the group for researchers who complained that full disclosure was an invasion of their financial privacy.

There was also concern about how to best highlight disclosure information without overemphasizing its importance or potential risk to a study's integrity.

Some respondents said their consent form highlights the information in bold type, while others place it strategically in the document—at the very beginning, for example.

Many also emphasized that the informed consent process should include a discussion of conflict of interest, not just a read-through of the document.

"Our data suggest that it will be difficult to achieve agreement on the issue of substantial understanding of financial interests," the researchers concluded. "Before we can resolve what counts as substantial understanding, there must be agreement about what risks are important for potential research participants to understand." ■