

PROFESSION

Financial ties to industry widespread on clinical guideline panels

A study finds committees controlled by experts with conflicts of interest such as owning stock in companies that could be affected by their recommendations.

By **KEVIN B. O'REILLY**, *amednews* staff. *Posted April 11, 2011.*

More than half of the people serving on cardiovascular guideline-writing committees between 2004 and 2008 had financial conflicts, according to a March 28 *Archives of Internal Medicine* study that sheds new light on the pervasiveness of financial ties to industry among the experts who make the clinical recommendations that shape medical care.

The new data arrived only days after an Institute of Medicine panel proposed wide-reaching standards on how clinical guideline panels should manage and limit conflicts of interest.

Of nearly 500 people working on 17 guidelines issued jointly by the American College of Cardiology and the American Heart Assn., 56% reported financial relationships with industry related to the clinical area covered by their committee. Eleven of the 17 guideline panels had a majority of members disclosing conflicts of interest such as receiving pay for research, speaking, consulting, advising or owning stock in companies that could be affected by the committee's recommendations.

In some cases, researchers found, the panels were dominated by experts with financial conflicts. Nearly 90% of people serving on a 2007 guideline panel on intracerebral hemorrhage reported conflicts of interest, and nearly 80% of the members on separate committees covering device-based therapy of cardiac rhythm abnormalities and care of unstable angina had financial relationships with industry.

The findings are worrisome, said Bernard Lo, MD, director of the University of California, San Francisco, School of Medicine's Program in Medical Ethics.

"Anytime there are that many people on the guideline panel with ties to industry, it can really undermine the credibility and trustworthiness of the guideline," said Dr. Lo, who chaired a 2009 IOM panel that issued a broad-ranging report on conflicts of interest.

In a joint statement, the ACC and the AHA said they "remain fully committed to transparency in the development of all our guidelines. We will continue to look closely at our policies regarding relationships with industry and welcome public dialogue that may help us continue to enhance our practices in the future."

Industry standard

Indeed, it is the heart organizations' transparency -- all financial-conflict disclosures are published as an appendix to each guideline -- that enabled the *Archives* study. Last year, the ACC and AHA adopted stricter conflict-of-interest policies, and the college helped shape a code on interactions with industry adopted by the Council of Medical Specialty Societies in 2010 and revised in March.

Thirty-four health professional societies had signed on to the code at this article's deadline. The code says a majority of guideline panel members, and the committee's chair, should have no financial conflicts relevant to the area covered. Also, organizations should bar direct industry support of guideline development and publish panelists' financial disclosure information.

The manner in which financial conflicts are managed is maturing, said James N. Kirkpatrick, MD, senior author of the *Archives* study.

"The dominant way of dealing with conflicts of interest has been disclosure, but there is an increasing trend toward not just disclosure [but] dealing with conflicts," said Dr. Kirkpatrick, assistant professor in the Division of Cardiovascular Medicine and associate fellow in the Center for Bioethics at the University of Pennsylvania.

New strategies for managing conflicts include "prohibition from participating in guideline panels, not having a vote on the committee, having [conflicted] people serve as outside advisers, and requiring divestment of conflicts before participating in these guideline processes," he said. That 44% of cardiovascular guideline panelists had no industry ties shows there are many qualified experts who can help craft clinical recommendations, he added.

Redefining conflict

The IOM's March report goes even further in defining what constitutes a potential conflict for experts serving on guideline committees. Panelists should disclose all relevant current and planned commercial, institutional and

intellectual activities, as well as any related services that generate a "substantial proportion of income" for the physician or health professional, the report says.

"If you're doing a guideline on a topic and that procedure is one where you're making hundreds of thousands of dollars per year in income, that may be more of a financial conflict than owning \$10,000 worth of stock," said Earl P. Steinberg, MD, vice chair of the IOM panel and senior vice president of clinical strategy, quality and outcomes at WellPoint Inc. "In the past, those types of things have been given a pass."

The IOM report, "Clinical Practice Guidelines We Can Trust," calls on guideline development committees to make public the decision-making processes they use, employ a balanced, multidisciplinary group of experts, have patient advocates as panelists, use high-caliber systematic reviews, seek a wide range of external reviewers, and clearly explain what care is being recommended and why.

"At the end of the day," Dr. Steinberg said, "guidelines are of no value if they aren't put into practice, and one of the factors that will determine that is the extent to which [physicians] believe in them and in the process with which they were developed."

ADDITIONAL INFORMATION:

New standards for clinical guidelines

Developing objective, scientifically valid clinical practice guidelines requires careful management of financial conflicts, according to an Institute of Medicine report released in March. As part of a broader set of proposed standards, the IOM said guideline-writing committees should require that:

- Potential panel members disclose in writing all current and planned commercial, noncommercial, intellectual and institutional activities pertinent to the potential scope of the clinical practice guideline, including services from which they derive a substantial proportion of income.
- Each panel member's financial conflicts be reported and discussed by the group before starting guideline development work.
- All guideline panel members divest themselves of financial investments they or their family members have in entities whose interests could be affected by the clinical recommendations.
- Panel members with financial conflicts represent a minority of the committee.
- The chair or co-chairs of the panel have no financial conflicts.
- Entities such as physician organizations that fund the panel have no role in the guideline-development process.

Source: "Clinical Practice Guidelines We Can Trust," Institute of Medicine, March 23 (www.iom.edu/reports/2011/clinical-practice-guidelines-we-can-trust)

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"Conflicts of Interest in Cardiovascular Clinical Practice Guidelines," *Archives of Internal Medicine*, March 28 (archinte.ama-assn.org/cgi/content/abstract/171/6/577)

"Clinical Practice Guidelines We Can Trust," Institute of Medicine, March 23 (www.iom.edu/reports/2011/clinical-practice-guidelines-we-can-trust)

"Illuminating Physicians' Financial Relationships With Industry," *Archives of Internal Medicine*, March 28 (archinte.ama-assn.org/cgi/content/extract/171/6/587)

"Conflicts of Interest in Medical Research, Education and Practice," Institute of Medicine, April 21, 2009 (www.iom.edu/reports/2009/conflict-of-interest-in-medical-research-education-and-practice)

"Code for Interactions With Companies," Council of Medical Specialty Societies, March (www.cmss.org/uploadedfiles/site/cmss_policies/cmss_code_for_interactions_with_companies_approved_revised_version_3-19-11clean.pdf)

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