

IOM Issues 16 Conflict of Interest Recommendations

BY MARY ELLEN SCHNEIDER

Physicians should stop accepting gifts or meals from industry representatives, according to a report from the Institute of Medicine that offers 16 recommendations aimed at limiting financial conflicts of interest in medicine.

While some relationships with industry are beneficial, the widespread industry ties that have become common among physicians and researchers could undermine public confidence in medicine, according to the report from the IOM Committee on Conflict of Interest in Medical Research, Education, and Practice.

"This is a vital issue that really goes to the heart of patients' trust that they are receiving the best medical advice and medical care," Dr. Bernard Lo, chair of the IOM committee and director of the program in medical ethics at the University of California, San Francisco, said at a press briefing.

In the 300-plus page report, the IOM committee provides recommendations for physicians and institutions to identify and manage financial conflicts of interest in medical research, education, and practice. The report focuses specifically on financial relationships with pharmaceutical, medical device, and biotechnology companies.

First, all institutions engaged in medical research, education, and practice should establish conflict of interest policies that require all physicians, researchers, and senior officials to disclose their ties to industry. The committee also recommended that the medical community come together to create a universal, standardized, electronic disclosure form.

Beyond these voluntary disclosure efforts, the IOM committee recommended that Congress require drug and device makers and industry foundations to publicly report any payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease groups, continuing medical education (CME) providers, and related foundations.

This type of searchable public database would allow medical institutions and journal publishers to verify the disclosure information they receive from researchers and physicians, the committee said.

While disclosure of financial ties was a major focus of the committee's recommendations, institutions also must act to prohibit certain relationships with industry and strictly manage others, Dr. Lo said. "Disclosure is a necessary first step, but it's a limited first step," Dr. Lo said. "If you don't disclose relationships to the institution you work for, they can't figure out what to do."

In addition to refusing to accept gifts and meals from industry, the IOM committee recommended that physicians set restrictions on their contacts with sales representatives and use drug samples only for patients who can't afford medications. The committee also recom-

mended that physicians enter into only bona fide consultation arrangements with industry provided that these include written contracts. The report includes similar recommendations for faculty, students, residents, and fellows at academic medical centers.

The IOM committee also challenged the medical community to come up with a new system for funding accredited CME that would be free of industry influence.

The report also addressed industry influence in the development of clinical practice guidelines. The committee recommended that groups involved in guideline development not accept direct funding from industry. Additionally, they should try to exclude individuals with conflicts of interest from serving on guideline development panels. If the necessary expertise can't be obtained from experts who are free of conflict, the IOM committee advised that conflicted individuals should be a minority on the panel and should be barred from voting on any topics in which they have a financial interest. The committee also recommended that the chair of the guideline panel be free of conflicts.

In the research arena, the IOM committee recommended that, in general, investigators should not conduct research involving human subjects if they have a financial stake in the outcome of the study. Exceptions are possible but should be made only if the researcher's participation is considered essential to the safety of the research. Even then, a conflict of interest committee should approve the involvement and consider placing restrictions on his or her role in the study, the committee said.

The Pharmaceutical Research and Manufacturers of America (PhRMA) was still reviewing the IOM report at press time. However, the group cautioned policy makers and the medical community to balance the need to manage potential conflicts of interest against the possibility that "overly restrictive policies" could have unintended consequences. For example, prohibitions on the use of drug samples or on industry funding for CME could negatively affect patient care, according to the group.

"Interactions between pharmaceutical sales representatives and health care professionals enhance public health and improve patient care," Ken Johnson, PhRMA senior vice president, said in a statement. "Pharmaceutical research companies take this responsibility seriously and remain committed to ensuring that these interactions follow the highest standards."

The IOM study was sponsored by the National Institutes of Health, the Robert Wood Johnson Foundation, the Greenwall Foundation, the American Board of Internal Medicine Foundation, the Burroughs Wellcome Fund, and the Josiah Macy Jr. Foundation. ■

The report is available at www.nap.edu/catalog.php?record_id=12598#toc.

POLICY & PRACTICE

Part A to Go Broke in 2017

The Medicare Hospital Insurance Trust Fund will run out of money in 2017—2 years earlier than predicted last year—in part because the fund is collecting fewer payroll taxes during the recession, trustees of the fund announced in their annual report. If lawmakers don't make changes in the program, in 2017 the Part A Hospital Insurance Trust Fund could pay only 81% of anticipated benefits, and that would decline to about 50% in 2035 and 30% in 2080, the trustees said. The trustees also predicted that premiums for Medicare Parts B and D will continue to rise much faster than inflation, and the separate Medicare Supplemental Insurance Trust Fund that in part finances those benefits will require additional money from the general treasury. Health and Human Services Secretary Kathleen Sebelius said in a statement that the report should stimulate action on the part of lawmakers considering overall health care reform. "This isn't just another government report," Ms. Sebelius commented. "It's a wake-up call for everyone who is concerned about Medicare and the health of our economy. And it's yet another sign that we can't wait for real, comprehensive health reform."

Mental Health Parity Comments Due

The federal government is seeking public comments before implementing a law that demands broader insurance coverage for mental health benefits. The Mental Health Parity and Addiction Equity Act of 2008 requires that health plans use the same rules for cost-sharing and visit limits in offering mental health and addiction treatment that they use for medical and surgical treatments. Together, HHS and the Labor Department said they want to know the financial and treatment limits that insurance plans currently impose, the plans' practices in determining medical necessity for and denying mental health benefits, and how plans handle out-of-network mental health benefits.

Families Can't Afford Insurance

The majority of uninsured American families cannot afford to buy nongroup health insurance, according to a study from the Agency for Healthcare Research and Quality. The study measured families' median net worth—their savings plus other assets, minus debt—rather than just family income. The AHRQ concluded that although an income-based model works well to estimate how many families will enroll in employer-based coverage, it overestimates nongroup health insurance enrollment for families that have low net worth and underestimates enrollment for families that have high net worth. Also, families without access to employer-based coverage were

much more likely than those with such access to earn below 200% of the federal poverty level, the study showed.

Medical Homes Are Challenging

Transforming a primary care practice into a patient-centered medical home (PCMH) requires "epic whole-practice reimagination and redesign," according to researchers who reported on one of the first demonstrations of the PCMH model. The results of the 2-year pilot project, which was launched in 2006 and supported by the American Academy of Family Physicians, showed that the technology that is needed to run a PCMH is especially difficult to implement. In addition, a successful transition to a PCMH requires physicians "to change their professional identity and the socialized ways they currently deliver primary care." For example, physicians must learn to work in practice teams, change how they manage chronic care, incorporate a populationwide approach to health management, use evidence at the point of care, and partner with their patients, the researchers wrote in the May/June *Annals of Family Medicine*.

HHS Launches Lupus Campaign

The Department of Health and Human Services, in cooperation with the American College of Rheumatology and other health care organizations, has launched a national advertising campaign to educate women about lupus. "Despite its prevalence in the United States, lupus is rarely discussed and often misunderstood among women in our country," said Dr. Wanda K. Jones, deputy assistant secretary for women's health at HHS. A recent study by the Ad Council found that about 80% of women aged 18-44 in the United States have little or no knowledge of lupus.

New Web Site Pushes Reform

Doctors for America, a new grassroots physician organization, is launching a campaign to get physicians' voices heard on health care reform. The "Voices of Physicians" campaign has collected and published comments from doctors nationwide at www.voicesofphysicians.org. The 11,000-member group, which started a year ago and was originally Doctors for Obama, has no outside funding and does not take a position on health reform, said its president, Dr. Vivek Murthy, during a teleconference. He noted, however, that "what we hear over and over from physicians is [that their concern is] not how much they're reimbursed but what they're reimbursed for. They want to spend more time with patients and do more that is patient centered."

—Jane Anderson