

IOM Guidelines Aim to Curb Conflicts of Interest

BY MARY ELLEN SCHNEIDER

Physicians should stop accepting gifts or meals from industry representatives, according to a new 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 patient's 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 during a press briefing.

In a 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.

For starters, 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 to cut down on variation and reduce administrative burdens for physicians.

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 disclosure information from researchers and physicians, the committee said.

While disclosure of financial ties was a major focus of the committee's recommendations, it was only the beginning. Institutions also must act to prohibit certain relationships with industry and strictly manage others, Dr. Lo said.

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 recommended that physicians enter into only bona fide consultation arrangements with industry provided that these include written contracts and that physicians avoid presenting or publishing any material whose contract is controlled or ghostwritten by industry.

The IOM committee also challenged the medical community to come up with a new system for funding accredited CMEs 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 for 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 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 continuing medical education could negatively affect patient care, according to the group.

"In the end, 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

Psych Care Often Inaccessible

Two-thirds of primary care physicians said they couldn't get outpatient mental health services for their patients, according to a study by the Center for Studying Health System Change. The 2004-2005 data are from the center's Community Tracking Study Physician Survey and other sources. A total of 67% of primary care physicians said they couldn't access mental health services for patients, compared with 34% who said they couldn't get specialist referrals and 30% who had trouble getting diagnostic imaging. Problems related to health plan barriers, inadequate insurance coverage, and shortages of providers. The study, funded by the Commonwealth Fund, was published in the online version of the journal *Health Affairs*.

CMS Considers Hospice Rule

Physicians certifying patients for Medicare-covered hospice stays would be required to write a brief explanation of why a patient has 6 months or less to live, under a new rule proposed by the Centers for Medicare and Medicaid Services. Currently, physicians need only sign a certification to qualify someone for hospice services, although the CMS also requires the medical record to include documentation supporting a terminal prognosis. However, the Medicare Payment Advisory Commission has noted an increasing number of hospice patients with stays longer than 180 days, and the proposed rule is designed to provide more accountability for hospice certification, the CMS said. Comments, including whether the requirement would increase physician engagement in the certification process, are due by June 22.

Medical Discipline Declined

State medical boards seriously disciplined far fewer doctors in 2007 and 2008 than they did in 2004, the peak year for such actions against doctors, according to an analysis by the consumer-advocacy group Public Citizen. In 2008, there were 2.92 serious disciplinary actions per 1,000 physicians, the same rate as in 2007 but 21% lower than in 2004. The states that disciplined the most doctors per 1,000 practitioners were Alaska, Kentucky, Ohio, Arizona, Oklahoma, North Dakota, Louisiana, Iowa, Colorado, and Maine. Minnesota disciplined the fewest physicians, and California, Florida, Maryland, South Carolina, and Wisconsin ranked low on the list, Public Citizen said. The annual rankings are based on data from the Federation of State Medical Boards. Serious disciplinary actions include license revocations and surrenders, suspensions, and probation with restrictions on practice.

Proposed Dialysis Policy Risky

A proposed change in Medicare reimbursement policy could make it more difficult for African Americans

with kidney disease to access dialysis services, a study in the *Journal of the American Society of Nephrology* suggested. Under the possible policy change, CMS would make a single bundled payment to dialysis units to cover both dialysis and injectable medications, which have been reimbursed separately. The analysis of 12,000 patients starting dialysis found that African Americans had lower initial hemoglobin levels, compared with readings in whites who were beginning treatment. The study also found that the average required dose of erythropoiesis-stimulating agents over the first 2 months of dialysis was 11% higher in African American patients. Since dialysis centers no longer will be reimbursed more for the higher doses, the researchers said they are concerned that the new policy could create a financial disincentive for centers to accept African Americans. "If race is not included as a payment adjuster, African Americans could be disadvantaged by this policy change," asserted study coauthor Dr. Areef Is-hani of the University of Minnesota.

PhRMA Revises Trial Standards

The Pharmaceutical Research and Manufacturers of America has revised its voluntary standards for how drug manufacturers run clinical trials and communicate trial results. The new PhRMA standards call on drug makers to register on a public Web site all interventional clinical trials—including some phase I studies. The standards also call for companies to "greatly expand transparency in medical research" by providing summaries of results from for all interventional clinical trials, regardless of whether the research is discontinued or the medication being studied is ever approved. Finally, the new standards call for drug makers to adopt the authorship standards of the International Committee of Medical Journal Editors. The committee says, for instance, that only individuals who make substantial contributions to a manuscript should be included as authors.

Routine HIV Testing Urged

The American College of Physicians and the Infectious Disease Society of America have jointly called for routine HIV testing for sexually active adults, pregnant women, and newborns. Federally supported health care programs should provide coverage for such testing, said the policy statement published in *Clinical Infectious Diseases*. Public health officials also should promote evidence-based interventions to minimize the risk of HIV transmission—comprehensive sex education, condom distribution, and syringe-exchange programs—the two groups said. They also urged that all patients living with HIV/AIDS in the United States have access to care provided by physicians trained in AIDS treatment.

—Jane Anderson